

US3212013 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:44:16

All time stamps listed in this document are displayed in GMT

US3212013

Form: Participant Creation

Data signed: (b) (4) 26 Mar 2021 17:23:36

Generated On: 09 Jun 2021 15:44:16

Participant ID

US3212013

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

US3212013

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

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

Visit date (dd MMM yyyy)	03 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3212013

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
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

US3212013

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Date of Informed Consent (*dd MMM yyyy*) 03 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

US3212013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3212013

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	8 DEC 1993
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)	8 DEC 1993
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1993
Start Year (derived)	1993
Stop Month and Year (derived)	DEC 1993
Stop Year (derived)	1993

US3212013

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	31 AUG 1998
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)	31 AUG 1998
Stop date completely unknown	False
Start Month and Year (derived)	AUG 1998
Start Year (derived)	1998
Stop Month and Year (derived)	AUG 1998
Stop Year (derived)	1998

US3212013

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	25 JUN 2002
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)	25 JUN 2002
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JUN 2002
Stop Year (derived)	2002

US3212013

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	CHOLECYSTECTOMY
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

US3212013

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	CHOLELITHIASIS
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

US3212013

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	25 JUN 2002
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)	25 JUN 2002
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JUN 2002
Stop Year (derived)	2002

US3212013

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	SEASONAL ALLERGIES
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)	

US3212013

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	IRON DEFICIENCY ANEMIA
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)	

US3212013

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	PERONEAL TEAR
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

US3212013

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	PERONEAL TENDON REPAIR
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	INTRAMURAL UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2012
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)	22 SEP 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	SEP 2020
Stop Year (derived)	2020

US3212013

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Condition	OBESITY
Start date (dd MMM yyyy)	03 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3212013

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:06 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 14:06
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	200 lb
BMI (<i>xxx.x</i>)	36.65696 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)	

US3212013

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 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) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Date of assessment (dd MMM yyyy) 03 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) 25 JUN 2002

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3212013

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 26 Mar 2021 17:23:39

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	True
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PARTICIPANT LIVES WITH CHILDREN IN THE HOUSEHOLD LIKELY TO GO BACK TO SCHOOL IN PERSON THIS YEAR

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

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

Visit date (dd MMM yyyy)	03 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3212013

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 100752

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 ☒

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Height	ND - Not Done
Weight	ND - Not Done

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 14:06
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 16:52
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3212013

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 03 AUG 2020

What was the treatment time? (00:00-23:59) 16:19 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 16:19

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) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

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

Collection date (dd MMM yyyy)	03 AUG 2020
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Collection time (00:00-23:59)	15:37 (24 HR)
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Collection date and time (derived)	03 AUG 2020 15:37
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US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)			03 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	03 AUG 2020 15:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 16:55

PC Open Date & Time

03 AUG 2020 16:39

PC Close Date & Time

03 AUG 2020 19:09

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	03 AUG 2020 21:40
PC Open Date & Time	03 AUG 2020 20:04
PC Close Date & Time	04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

04 AUG 2020 18:06

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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 17:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

06 AUG 2020 14:54

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 18:08

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

08 AUG 2020 18:05

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 12:48

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 16:56

PC Open Date & Time

03 AUG 2020 16:39

PC Close Date & Time

03 AUG 2020 19:09

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 21:41

PC Open Date & Time

03 AUG 2020 20:04

PC Close Date & Time

04 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 16:27

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 17:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 14:49

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 18:06

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 16:56
PC Open Date & Time	03 AUG 2020 16:39
PC Close Date & Time	03 AUG 2020 19:09

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 21:41
PC Open Date & Time	03 AUG 2020 20:04
PC Close Date & Time	04 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 16:28
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 17:39
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 14:50
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:09
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2656

EAB) (1725)

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:06
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:49
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3212013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

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

Visit date (dd MMM yyyy)	07 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	14:58 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 14:58
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 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)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	07 OCT 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 16:28
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3212013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 07 OCT 2020

What was the treatment time? (00:00-23:59) 15:43 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 15:43

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

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

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

Collection date (dd MMM yyyy)	07 OCT 2020
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Collection time (00:00-23:59)	15:25 (24 HR)
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Collection date and time (derived)	07 OCT 2020 15:25
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US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:20	07 OCT 2020 15:20
Nasopharyngeal Swab 2	No		

US3212013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 16:20

PC Open Date & Time

07 OCT 2020 16:03

PC Close Date & Time

07 OCT 2020 18:33

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.1 °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	07 OCT 2020 22:20
PC Open Date & Time	07 OCT 2020 19:28
PC Close Date & Time	08 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

08 OCT 2020 13:56

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 22:21

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 18:20

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 00:00

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °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

13 OCT 2020 00:47

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

13 OCT 2020 22:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 16:21

PC Open Date & Time

07 OCT 2020 16:03

PC Close Date & Time

07 OCT 2020 18:33

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 22:21

PC Open Date & Time

07 OCT 2020 19:28

PC Close Date & Time

08 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 13:57

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 22:21

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 18:19

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 00:00

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 00:48

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 22:28

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 16:21
PC Open Date & Time	07 OCT 2020 16:03
PC Close Date & Time	07 OCT 2020 18:33

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 22:22
PC Open Date & Time	07 OCT 2020 19:28
PC Close Date & Time	08 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 13:57
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 22:21
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 18:19
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 00:48
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 22:28
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

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

Visit date (dd MMM yyyy)	04 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	14:24 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 14:24
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

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

Collection date (dd MMM yyyy)	04 NOV 2020
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Collection time (00:00-23:59)	15:21 (24 HR)
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Collection date and time (derived)	04 NOV 2020 15:21
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US3212013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:40

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 OCT 2020 14:31:59
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 00:20:48

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 02:40:54

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 17:15:30

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 00:48:32

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 00:32:09

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 19:14:45

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 17:59:51
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 00:01:29

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 13:39:30

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 01:45:39

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 01:15:00

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 11:07:51

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 00:06:53

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 15:33:20

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 00:01:37
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 00:03:12

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 14:19:14

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 00:42:59

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 14:09:46

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 02:08:52

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 00:01:47

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 236

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 01:45:16

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 250

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 00:01:28

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 16:22:58

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 285

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 292

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 341

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 376

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Patient Cloud Open Date & Time	11 AUG 2021 00:01
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Patient Cloud Close Date & Time	15 AUG 2021 23:59
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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Patient Cloud Open Date & Time	18 AUG 2021 00:01
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Patient Cloud Close Date & Time	22 AUG 2021 23:59
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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Patient Cloud Open Date & Time	06 OCT 2021 00:01
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Patient Cloud Close Date & Time	10 OCT 2021 23:59
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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 467

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 495

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 530

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 572

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 579

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 593

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

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

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

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

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

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

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 684

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3212013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:44:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 14:09:54

US3212013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 18:44:10

Generated On: 09 Jun 2021 15:44:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	07 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 18:44:10

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 APR 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	07 APR 2021 12:15
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 18:44:09

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 18:44:09

Generated On: 09 Jun 2021 15:44:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	07 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	12:49 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	07 APR 2021 12:49
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US3212013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 18:44:09

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

Date of Contact	31 AUG 2020
Time of Contact	14:50
Date and Time of Contact (derived)	31 AUG 2020 14:50
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 AUG 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

Date of Visit	31 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	31 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Apr 2021 19:17:03

Generated On: 09 Jun 2021 15:44:16

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 17:23:38

Generated On: 09 Jun 2021 15:44:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	3 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 17:55:10

Generated On: 09 Jun 2021 15:44:16

Date of updated informed consent (dd MMM yyyy) 3 FEB 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) 3 FEB 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 _____

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:23:38

Generated On: 09 Jun 2021 15:44:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	3 FEB 2021
-------------------------------	------------

Collection time (00:00-23:59)	11:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	3 FEB 2021 11:56
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US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 17:23:38

Generated On: 09 Jun 2021 15:44:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 FEB 2021
Collection time (00:00 - 23:59)	11:52
Collection Date and Time (derived)	3 FEB 2021 11:52

US3212013

Folder: **Unscheduled 29 Sep 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Visit Date	29 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:47 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:47
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212013

Folder: **Unscheduled 31 Aug 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Visit Date	31 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	True
Pregnancy Test	False

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:13 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 16:13
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	31 AUG 2020
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Collection time (00:00-23:59)	16:35 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	31 AUG 2020 16:35
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US3212013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

AEID	USA-US115-2020-MRNA-1273-P30 1000003
Adverse event	ABNORMAL UTERINE BLEEDING
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)	27 AUG 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 AUG 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 checked="" type="radio"/> Grade 4 <input 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)	27 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	28 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" 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	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	

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

PATIENT HAS A HISTORY OF
UTERINE FIBROIDS. ON
27AUG2020 SHE PRESENTED TO
MEMORIAL HERMANN
HOSPITAL WITH UTERINE
HEMORRHAGE. SHE WAS
ADMITTED TO HOSPITAL AND
RECEIVED 3 PINTS OF
TRANSFUSED BLOOD. SHE WAS
PRESCRIBED HORMONAL
CONTRACEPTION AS WELL.
SHE WAS DISCHARGED ON
28AUG2020. RECORDS WILL BE
REQUESTED BY SITE. IP IS
BEING DELAYED DUE TO
PARTICIPANT'S RECEIVING
BLOOD TRANSFUSIONS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 OCT 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 OCT 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 (3)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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)	_____

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

AEID	USA-US115-2020-MRNA-1273-P30 1000013
Adverse event	ABNORMAL UTERINE BLEEDING
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)	22 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)	22 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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 UNDERWENT HYSTERECTOMY FOR UTERINE BLEEDING/FIBROIDS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 14:51:10

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AEID	
Adverse event	RIGHT FOOT PAIN (PLANTAR FASCIITIS)
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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	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 (6)

Data signed: (b) (4) 06 Apr 2021 14:51:10

Generated On: 09 Jun 2021 15:44:16

AEID	
Adverse event	VAGINAL CANDIDIASIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 OCT 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

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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	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 checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
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) 26 Mar 2021 17:23:37

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication OXYBUTYNIN

Prophylaxis Yes ☐
No ☒

Indication URINARY INCONTINENCE

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 (1)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (2)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication ESMOPRAZOLE (NEXIUM)

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Name of Medication FERROUS SULPHATE

Prophylaxis Yes ☐
No ☒

Indication IRON DEFICIENCY

Dose per administration 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 (3)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication CETIRIZINE (ZYRTEC)

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (4)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication PROVERA

Prophylaxis Yes ☐
No ☒

Indication UTERINE BLEEDING

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 (5)

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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)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication SPRINTEC
(NORGESTIMATE/ETHINYL
ESTRADIOL)

Prophylaxis Yes ☐
No ☒

Indication UTERINE BLEEDING

Dose per administration 0.25/0.035

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

TAKE 1 EVERY 6 HOURS X 4
DAYS, THEN TAKE 1 EVERY 8
HRS X 3 DAYS, THEN TAKE 1
EVERY 12 HRS X 2 DAYS, THEN
TAKE 1 DAILY

Route of administration Oral ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 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 (7)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication FERROUS SULPHATE

Prophylaxis Yes ☐
No ☒

Indication FE DEFICIENCY 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 (7)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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)	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 (8)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

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 (8)

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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)		23 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)		07 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 (9)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Name of Medication COLACE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION WITH
POSTOPERATIVE OPIOID USE;
HYSTERECTOMY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 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)	07 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

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 (10)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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)		07 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 (11)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Name of Medication NORCO
(HYDROCODONE/ACETAMINOPHEN)

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

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 (11)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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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)	22 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)		07 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) 26 Mar 2021 17:23:37

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Name of Medication LEVONORGESTREL/ETHINYL
ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication ABNORMAL UTERINE
BLEEDING

Dose per administration 0.1/0.02

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 (12)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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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)	05 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)	21 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication AMOXICILLIN CLAVULANATE

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 500/125

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 (13)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Mar 2021 17:23:37

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication FOOT PAIN

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

TAPERED DOSE: 6 TODAY, 5
TOMORROW, 4 ON 30OCT, 3 ON
31OCT, 2 ON 1NOV, 1 ON 2NOV

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) 26 Mar 2021 17:23:37

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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)	28 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Name of Medication INFLUENZA VACCINATION

Prophylaxis Yes ☒
No ☐

Indication IMMUNIZATION

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 (16)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 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 (17)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Name of Medication FLUCONAZOLE (DIFLUCAN)

Prophylaxis Yes ☐
No ☒

Indication VAGINAL CANDIDIASIS

Dose per administration 150

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 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)		20 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 (18)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Name of Medication NYSTATIN

Prophylaxis Yes ☐
No ☒

Indication VAGINAL CANDIDIASIS

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 17:23:38

Generated On: 09 Jun 2021 15:44:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 17:23:37

Generated On: 09 Jun 2021 15:44:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 AUG 2020	BLOOD TRANSFUSION	Adverse Event	
22 SEP 2020	ELECTIVE HYSTERECTOMY	Medical History	

US3212013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:44:16

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3212013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:44:16

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	01/SEP/2020 11:51
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	30/SEP/2020 15:29
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:31
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:34
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	27/OCT/2020 10:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	06/NOV/2020 11:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	24/NOV/2020 08:00
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/NOV/2020 14:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/NOV/2020 16:04
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 06 Apr 2021 23:32:09

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	22/DEC/2020 18:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Mar 2021 17:23:39

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-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 type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 06 Apr 2021 23:32:08

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 06 Apr 2021 23:32:08

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/NOV/2020 16:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 06 Apr 2021 23:32:08

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/JAN/2021 10:52
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 06 Apr 2021 23:32:08

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/MAR/2021 14:27
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

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 06 Apr 2021 23:32:08

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 12:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 06 Apr 2021 23:32:08

Generated On: 09 Jun 2021 15:44:16

SAEID	USA-US115-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/APR/2021 12:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3212013 (Prod: DM Clinical Research - ERN - PPDS)

US3212013

Form: Participant Creation

Generated On: 09 Jun 2021 15:44:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'US3212013'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:19

US3212013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:25:45

US3212013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:20

US3212013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Aug 2020 20:25:45

US3212013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'SCRN'	System	03 Aug 2020 20:25:45

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:21

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '45'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'YEARS'	System	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '45'	System	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Female (F)'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:44:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:26:35

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:35:23
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Aug 2020'	System	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2020'	System	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:27:34

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:20

US3212013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:44:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'I'	System	03 Aug 2020 20:28:18

US3212013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:44:16

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:28:18

US3212013

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:44:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:28:52

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:33:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:33:04
Data point term sent to Coder	System	03 Aug 2020 20:31:44
User entered 'Cesarean Section'	(b) (4), (b) (6)	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '8 Dec 1993'	(b) (4), (b) (6)	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '8 Dec 1993'	(b) (4), (b) (6)	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Dec 1993'	System	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '1993'	System	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Dec 1993'	System	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '1993'	System	03 Aug 2020 20:31:21

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:33:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:33:04
Data point term sent to Coder	System	03 Aug 2020 20:32:46
User entered 'Cesarean Section'	(b) (4), (b) (6)	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '31 Aug 1998'	(b) (4), (b) (6)	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '31 Aug 1998'	(b) (4), (b) (6)	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Aug 1998'	System	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '1998'	System	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Aug 1998'	System	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '1998'	System	03 Aug 2020 20:32:18

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:35:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:35:06
Data point term sent to Coder	System	03 Aug 2020 20:33:49
User entered 'Cesarean Section'	(b) (4), (b) (6)	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25 Jun 2002'	(b) (4), (b) (6)	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25 Jun 2002'	(b) (4), (b) (6)	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jun 2002'	System	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2002'	System	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jun 2002'	System	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2002'	System	03 Aug 2020 20:33:48

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:35:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:35:07
Data point term sent to Coder	System	03 Aug 2020 20:34:49
User entered 'Cholecystectomy'	(b) (4), (b) (6)	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2016'	System	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2016'	System	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2016'	System	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2016'	System	03 Aug 2020 20:34:40

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:37:08
Data point term sent to Coder	System	03 Aug 2020 20:35:50
User entered 'Cholelithiasis'	(b) (4), (b) (6)	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2016'	(b) (4), (b) (6)	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2016'	System	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2016'	System	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2016'	System	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2016'	System	03 Aug 2020 20:35:35

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:37:08
Data point term sent to Coder	System	03 Aug 2020 20:36:51
User entered 'Bilateral Tubal Ligation'	(b) (4), (b) (6)	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25 Jun 2002'	(b) (4), (b) (6)	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25 Jun 2002'	(b) (4), (b) (6)	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jun 2002'	System	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2002'	System	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jun 2002'	System	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2002'	System	03 Aug 2020 20:36:29

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:47:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:47:08
Data point term sent to Coder	System	03 Aug 2020 20:45:56
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2010'	(b) (4), (b) (6)	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2010'	System	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2010'	System	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:45:22

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 20:32:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 20:32:27
Data point term sent to Coder	System	26 Oct 2020 20:31:22
Coding entries removed.	Afifah Ayub (b) (4)	26 Oct 2020 20:30:52
User entered 'IRON DEFICIENCY anemia' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:30:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Iron and trace metal metabolism disorders, HLT: Iron deficiencies, PT: Iron deficiency, LLT: Iron deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:47:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:47:08
Data point term sent to Coder	System	03 Aug 2020 20:45:57
User entered 'Iron Deficiency'	(b) (4), (b) (6)	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2018'	(b) (4), (b) (6)	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 20:49:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 20:49:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 20:49:54
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 20:45:45
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2018'	System	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2018'	System	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:45:45

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:47:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:47:08
Data point term sent to Coder	System	03 Aug 2020 20:46:58
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2017'	(b) (4), (b) (6)	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 20:46:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 20:46:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 20:46:26
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 20:46:11
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2017'	System	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2017'	System	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:46:11

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:49:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:49:09
Data point term sent to Coder	System	03 Aug 2020 20:48:03
User entered 'Urinary Incontinence'	(b) (4), (b) (6)	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2019'	(b) (4), (b) (6)	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2019'	System	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2019'	System	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered empty.	System	03 Aug 2020 20:47:09

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Partial tear of muscle - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 07:01:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 07:01:41
Data point term sent to Coder	System	03 Aug 2020 20:48:01
User entered 'Peroneal Tear'	(b) (4), (b) (6)	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	03 Aug 2020 20:48:46
User entered 'UN Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 20:48:46
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	03 Aug 2020 20:47:46
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 20:48:46
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 20:47:46
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 20:48:46
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Feb 2020'	System	03 Aug 2020 20:48:46
User entered empty.	System	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2020'	System	03 Aug 2020 20:48:46
User entered empty.	System	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Feb 2020'	System	03 Aug 2020 20:48:46
User entered empty.	System	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2020'	System	03 Aug 2020 20:48:46
User entered empty.	System	03 Aug 2020 20:47:46

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Tendon repair - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 13:30:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 13:30:51
Data point term sent to Coder	System	03 Aug 2020 20:50:04
User entered 'Peroneal Tendon Repair'	(b) (4), (b) (6)	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN Feb 2020'	(b) (4), (b) (6)	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN Feb 2020'	(b) (4), (b) (6)	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Feb 2020'	System	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2020'	System	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Feb 2020'	System	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2020'	System	03 Aug 2020 20:49:30

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:49:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:49:57
Data point term sent to Coder	System	26 Oct 2020 20:31:22
Coding entries removed.	Afifah Ayub (b) (4)	26 Oct 2020 20:30:32
User entered 'intramural UTERINE FIBROIDS' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:30:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:45:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:45:38
Data point term sent to Coder	System	29 Sep 2020 19:44:23
User entered 'Uterine fibroids'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2012'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:30:32
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:30:32
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Jan 2012'	System	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2012'	System	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'Sep 2020'	System	26 Oct 2020 20:30:32
User entered empty.	System	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '2020'	System	26 Oct 2020 20:30:32
User entered empty.	System	29 Sep 2020 19:43:33
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:18
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	20 Aug 2020 17:32:07

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:46:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:45:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 19:45:39
Data point term sent to Coder	System	29 Sep 2020 19:45:27
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
Data point term sent to Coder	System	29 Sep 2020 19:44:23
User entered 'Obesity'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 18:45:21
Query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' answered with 'subject diagnosed with obesity at screening visit. data correct as entered.' (Site from DM).	Reagan Reed (b) (4)	16 Oct 2020 21:03:59
User opened query 'Per CDM: "Medical history start date" and 'Date of Informed Consent' are on the same day. please review and update as per CCGs page 22. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:08:14
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered '03 Aug 2020'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered 'Aug 2020'	System	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered '2020'	System	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered empty.	System	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:44:16

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
DataPoint activated with code reason code Data required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:47
DataPoint inactivated with code reason code Data not required.	Afifah Ayub (b) (4)	29 Sep 2020 19:44:32
User entered empty.	System	29 Sep 2020 19:43:44

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:35:40
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14:06'	(b) (4), (b) (6)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered '03 Aug 2020 14:06'	System	07 Dec 2020 16:35:40
User entered '3 Aug 2020 14:06'	System	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '62' in	(b) (4), (b) (6)	03 Aug 2020 20:55:19
DataPoint set to visible.	System	03 Aug 2020 20:28:18

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '200' lb	(b) (4), (b) (6)	03 Aug 2020 20:55:19
DataPoint set to visible.	System	03 Aug 2020 20:28:18

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
Amendment Manager: User entered '36.65696'	System	16 Sep 2020 23:41:44
User entered '36.7'	System	03 Aug 2020 20:55:19
DataPoint set to visible.	System	03 Aug 2020 20:28:18

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'kg/m2'	System	03 Aug 2020 20:55:19
DataPoint set to visible.	System	03 Aug 2020 20:28:18

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered '97.4' F	(b) (4), (b) (6)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:02:48
User entered 'Other (Other)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:02:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered '68'	(b) (4)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'bpm'	System	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered '12'	(b) (4)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'breaths/min'	System	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered '142'	(b) (4)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'mmHg'	System	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:32:49
User entered '92'	(b) (4)	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User entered 'mmHg'	System	03 Aug 2020 20:55:19

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40

US3212013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40

US3212013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 20:56:00

US3212013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:35:47
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:25:44
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		02 Sep 2020 17:13:23
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 20:56:00

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:35:53
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	03 Aug 2020 21:00:19
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	03 Aug 2020 20:57:53
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25 Jun 2002'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 21:00:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:00:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 21:00:19
User entered 'UN UNK ' (non-conformant).	(b) (4), (b) (6)	03 Aug 2020 21:00:19
User entered '1 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:44:16

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 20:57:53

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

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)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:44:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:02:40
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Participant lives with children in the household likely to go back to school in person this year'	(b) (4), (b) (6)	03 Aug 2020 21:03:58

US3212013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 31AUG2020 is not updated in EDC. Please review if the Immunogenicity sample has also been collected at the Unscheduled then add the details on page "Immunogenicity assessment" page under folder "Unscheduled 31AUG2020". ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 16:54:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 31AUG2020 is not updated in EDC. Please review if the Immunogenicity sample has also been collected at the Unscheduled then add the details on page "Immunogenicity assessment" page under folder "Unscheduled 31AUG2020". ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	14 Jan 2021 15:55:55
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 31AUG2020 is not updated in EDC. Please review if the Immunogenicity sample has also been collected at the Unscheduled then add the details on page "Immunogenicity assessment" page under folder "Unscheduled 31AUG2020". ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 11:31:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:05:43

US3212013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	10 Nov 2020 14:03:25
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 21:05:43

US3212013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Aug 2020 21:05:43

US3212013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'VISIT1'	System	03 Aug 2020 21:05:43

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:25

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:49:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:49:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 20:24:25
User entered '100752' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 20:24:25

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:08:59

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:08:59

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:08:59

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:08:59

US3212013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:44:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:08:59

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User accepted default value 'Pre-Dose (PREDOSE)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:34:53
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14:06'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered '03 Aug 2020 14:06'	System	07 Dec 2020 16:34:53
User entered '3 Aug 2020 14:06'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '97.4' F	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '68'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'bpm'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '12'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'breaths/min'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '142'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'mmHg'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '92'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'mmHg'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:44:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered missing code ND - Not Done.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:34:53
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 11:03:20
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'As per protocol, post-dose vitals are done at 30 minutes.' (Site from System).	Afifah Ayub (b) (4)	04 Aug 2020 14:27:15
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 13:20:40
User entered '16:52'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered '03 Aug 2020 16:52'	System	07 Dec 2020 16:34:53
User entered '3 Aug 2020 16:52'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '97.1' F	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '76'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'bpm'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '16'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'breaths/min'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '132'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'mmHg'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '84'	Afifah Ayub (b) (4)	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'mmHg'	System	04 Aug 2020 13:20:40

US3212013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:33:31
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 13:17:43

US3212013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:33:31
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 13:17:43

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Nirja Shah (b) (4)	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Nirja Shah (b) (4)	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020'	Nirja Shah (b) (4)	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '16:19'	Nirja Shah (b) (4)	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered '03 Aug 2020 16:19'	System	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Left Arm (LEFT ARM)'	Nirja Shah (b) (4)	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'ONCE'	System	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 21:21:20

US3212013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 13:17:06

US3212013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:35:04
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 13:17:06

US3212013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15:37'	Afifah Ayub (b) (4)	04 Aug 2020 13:17:06

US3212013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered '03 Aug 2020 15:37'	System	07 Dec 2020 16:35:04
User entered '3 Aug 2020 15:37'	System	04 Aug 2020 13:17:06

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL Swab sample dated 22AUG2020 for Unscheduled visit is present, however there is no swab dated 22AUG2020, please confirm the visit and dates for swab.Thnaks' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:45:22
Query 'Per GCL Lab Reconciliation: Swab: Per GCL Swab sample dated 22AUG2020 for Unscheduled visit is present, however there is no swab dated 22AUG2020, please confirm the visit and dates for swab.Thnaks' answered with 'subject was not seen on 22AUG, no swab collected on 22AUG, nothing in Lab portal for subject for 22AUG. unsure your query. please clarify ' (Site from DM).	Reagan Reed (b) (4)	21 Dec 2020 22:16:54
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL Swab sample dated 22AUG2020 for Unscheduled visit is present, however there is no swab dated 22AUG2020, please confirm the visit and dates for swab.Thnaks' (Site from DM).	(b) (4)	08 Dec 2020 06:11:34
User entered '03 Aug 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:35:10
User entered '3 Aug 2020'	Afifah Ayub (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15:30'	Afifah Ayub (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered '03 Aug 2020 15:30'	System	07 Dec 2020 16:35:10
User entered '3 Aug 2020 15:30'	System	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:51:54
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:51:54
User entered '15:30'	Afifah Ayub (b) (4)	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered empty.	System	25 Aug 2020 19:51:54
User entered '3 Aug 2020 15:30'	System	04 Aug 2020 13:16:21

US3212013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	18 Aug 2020 19:22:49

US3212013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	18 Aug 2020 19:22:49

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6'	System	03 Aug 2020 21:56:02
User entered 'Yes (Y)'	System	03 Aug 2020 21:56:02

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:47', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6'	System	03 Aug 2020 21:56:02
User entered '97.1'	System	03 Aug 2020 21:56:02

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6'	System	03 Aug 2020 21:56:02
User entered 'No (N)'	System	03 Aug 2020 21:56:02

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:55:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2a369c85-fcea-4af4-8ac8-8df56806feb6'	System	03 Aug 2020 21:56:02
User entered '03 Aug 2020 16:55'	System	03 Aug 2020 21:56:02

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 16:39'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 19:09'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc'	System	04 Aug 2020 02:41:06
User entered 'Yes (Y)'	System	04 Aug 2020 02:41:06

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc'	System	04 Aug 2020 02:41:06
User entered '98.7'	System	04 Aug 2020 02:41:06

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc'	System	04 Aug 2020 02:41:06
User entered 'No (N)'	System	04 Aug 2020 02:41:06

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:40:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b5d1886b-0339-4c7e-991b-71aff567f4cc'	System	04 Aug 2020 02:41:06
User entered '03 Aug 2020 21:40'	System	04 Aug 2020 02:41:06

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 20:04'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 2'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0'	System	04 Aug 2020 23:06:48
User entered 'Yes (Y)'	System	04 Aug 2020 23:06:48

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0'	System	04 Aug 2020 23:06:48
User entered '98.1'	System	04 Aug 2020 23:06:48

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0'	System	04 Aug 2020 23:06:48
User entered 'No (N)'	System	04 Aug 2020 23:06:48

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T18:06:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1dca15b2-7fe2-4e23-85eb-0f4eb84dd0e0'	System	04 Aug 2020 23:06:48
User entered '04 Aug 2020 18:06'	System	04 Aug 2020 23:06:48

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 3'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:38:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67'	System	05 Aug 2020 22:39:04
User entered 'Yes (Y)'	System	05 Aug 2020 22:39:04

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:38:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67'	System	05 Aug 2020 22:39:04
User entered '98.5'	System	05 Aug 2020 22:39:04

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:38:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67'	System	05 Aug 2020 22:39:04
User entered 'No (N)'	System	05 Aug 2020 22:39:04

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3e129890-8a99-4ee1-b409-1944c303ad67'	System	05 Aug 2020 22:39:04
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 22:39:04

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 4'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:53:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9'	System	06 Aug 2020 19:54:29
User entered 'Yes (Y)'	System	06 Aug 2020 19:54:29

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:54:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9'	System	06 Aug 2020 19:54:29
User entered '98.1'	System	06 Aug 2020 19:54:29

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:54:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9'	System	06 Aug 2020 19:54:29
User entered 'No (N)'	System	06 Aug 2020 19:54:29

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:54:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a7d27a98-bb6f-4c78-b3c8-6ec0c8e3c2e9'	System	06 Aug 2020 19:54:29
User entered '06 Aug 2020 14:54'	System	06 Aug 2020 19:54:29

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 5'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6'	System	07 Aug 2020 23:08:55
User entered 'Yes (Y)'	System	07 Aug 2020 23:08:55

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6'	System	07 Aug 2020 23:08:55
User entered '99.2'	System	07 Aug 2020 23:08:55

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6'	System	07 Aug 2020 23:08:55
User entered 'No (N)'	System	07 Aug 2020 23:08:55

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2256f277-331f-42ee-9d86-5f0945ea7db6'	System	07 Aug 2020 23:08:55
User entered '07 Aug 2020 18:08'	System	07 Aug 2020 23:08:55

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 6'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc'	System	08 Aug 2020 23:06:01
User entered 'Yes (Y)'	System	08 Aug 2020 23:06:01

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc'	System	08 Aug 2020 23:06:01
User entered '98.5'	System	08 Aug 2020 23:06:01

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc'	System	08 Aug 2020 23:06:01
User entered 'No (N)'	System	08 Aug 2020 23:06:01

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3378c207-e543-47df-8472-3f38738062fc'	System	08 Aug 2020 23:06:01
User entered '08 Aug 2020 18:05'	System	08 Aug 2020 23:06:01

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 7'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d'	System	09 Aug 2020 17:48:56
User entered 'Yes (Y)'	System	09 Aug 2020 17:48:56

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d' User entered '98.1'	System	09 Aug 2020 17:48:56
	System	09 Aug 2020 17:48:56

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d'	System	09 Aug 2020 17:48:56
User entered 'No (N)'	System	09 Aug 2020 17:48:56

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:48:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '542d05fa-90e9-4462-9c8b-191e5805de1d'	System	09 Aug 2020 17:48:56
User entered '09 Aug 2020 12:48'	System	09 Aug 2020 17:48:56

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820'	System	03 Aug 2020 21:56:36
User entered 'None (1)'	System	03 Aug 2020 21:56:36

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820'	System	03 Aug 2020 21:56:36
User entered 'No (N)'	System	03 Aug 2020 21:56:36

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820'	System	03 Aug 2020 21:56:36
User entered 'No (N)'	System	03 Aug 2020 21:56:36

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820'	System	03 Aug 2020 21:56:36
User entered 'None (1)'	System	03 Aug 2020 21:56:36

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cd0fa6cf-d9d3-4f95-a955-dada08283820'	System	03 Aug 2020 21:56:36
User entered '03 Aug 2020 16:56'	System	03 Aug 2020 21:56:36

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 16:39'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 19:09'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658'	System	04 Aug 2020 02:41:20
User entered 'None (1)'	System	04 Aug 2020 02:41:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:07', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658'	System	04 Aug 2020 02:41:20
User entered 'No (N)'	System	04 Aug 2020 02:41:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:11', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658'	System	04 Aug 2020 02:41:20
User entered 'No (N)'	System	04 Aug 2020 02:41:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658'	System	04 Aug 2020 02:41:20
User entered 'None (1)'	System	04 Aug 2020 02:41:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '883bf0ac-84f1-4c88-9ab1-e82e89d02658'	System	04 Aug 2020 02:41:20
User entered '03 Aug 2020 21:41'	System	04 Aug 2020 02:41:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 20:04'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 2'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:26:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326'	System	04 Aug 2020 21:27:14
User entered 'None (1)'	System	04 Aug 2020 21:27:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:26:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326'	System	04 Aug 2020 21:27:14
User entered 'No (N)'	System	04 Aug 2020 21:27:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:26:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326'	System	04 Aug 2020 21:27:14
User entered 'Yes (Y)'	System	04 Aug 2020 21:27:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326'	System	04 Aug 2020 21:27:14
User entered '1'	System	04 Aug 2020 21:27:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326'	System	04 Aug 2020 21:27:14
User entered 'None (1)'	System	04 Aug 2020 21:27:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '158a24ee-2c13-47f6-ba81-a70507ea8326'	System	04 Aug 2020 21:27:14
User entered '04 Aug 2020 16:27'	System	04 Aug 2020 21:27:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 3'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9'	System	05 Aug 2020 22:39:27
User entered 'None (1)'	System	05 Aug 2020 22:39:27

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9'	System	05 Aug 2020 22:39:27
User entered 'No (N)'	System	05 Aug 2020 22:39:27

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:16', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9'	System	05 Aug 2020 22:39:27
User entered 'No (N)'	System	05 Aug 2020 22:39:27

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9'	System	05 Aug 2020 22:39:27
User entered 'None (1)'	System	05 Aug 2020 22:39:27

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '328ea280-ac6f-4e9e-b087-9a22e7b77af9'	System	05 Aug 2020 22:39:27
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 22:39:27

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 4'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044'	System	06 Aug 2020 19:49:57
User entered 'None (1)'	System	06 Aug 2020 19:49:57

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044'	System	06 Aug 2020 19:49:57
User entered 'No (N)'	System	06 Aug 2020 19:49:57

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044'	System	06 Aug 2020 19:49:57
User entered 'No (N)'	System	06 Aug 2020 19:49:57

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044'	System	06 Aug 2020 19:49:57
User entered 'None (1)'	System	06 Aug 2020 19:49:57

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:49:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0da16527-71a8-4051-93b8-fd0756684044'	System	06 Aug 2020 19:49:57
User entered '06 Aug 2020 14:49'	System	06 Aug 2020 19:49:57

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 5'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:55', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722'	System	07 Aug 2020 23:09:16
User entered 'None (1)'	System	07 Aug 2020 23:09:16

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:08:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722'	System	07 Aug 2020 23:09:16
User entered 'No (N)'	System	07 Aug 2020 23:09:16

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722'	System	07 Aug 2020 23:09:16
User entered 'No (N)'	System	07 Aug 2020 23:09:16

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722'	System	07 Aug 2020 23:09:16
User entered 'None (1)'	System	07 Aug 2020 23:09:16

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '308ab892-3ec6-4fe8-9643-6e10055ea722'	System	07 Aug 2020 23:09:16
User entered '07 Aug 2020 18:09'	System	07 Aug 2020 23:09:16

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 6'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:05:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64'	System	08 Aug 2020 23:06:17
User entered 'None (1)'	System	08 Aug 2020 23:06:17

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64'	System	08 Aug 2020 23:06:17
User entered 'No (N)'	System	08 Aug 2020 23:06:17

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64'	System	08 Aug 2020 23:06:17
User entered 'No (N)'	System	08 Aug 2020 23:06:17

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64'	System	08 Aug 2020 23:06:17
User entered 'None (1)'	System	08 Aug 2020 23:06:17

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:11', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4010050e-1aa6-4979-81e9-eaada7296a64'	System	08 Aug 2020 23:06:17
User entered '08 Aug 2020 18:06'	System	08 Aug 2020 23:06:17

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 7'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9'	System	09 Aug 2020 17:49:14
User entered 'None (1)'	System	09 Aug 2020 17:49:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9'	System	09 Aug 2020 17:49:14
User entered 'No (N)'	System	09 Aug 2020 17:49:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9'	System	09 Aug 2020 17:49:14
User entered 'No (N)'	System	09 Aug 2020 17:49:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9'	System	09 Aug 2020 17:49:14
User entered 'None (1)'	System	09 Aug 2020 17:49:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '980c9b03-913a-4c66-a009-4d753d39cbc9'	System	09 Aug 2020 17:49:14
User entered '09 Aug 2020 12:49'	System	09 Aug 2020 17:49:14

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'None (0)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'None (0)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'None (0)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'None (0)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'None (0)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'None (0)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:50', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered 'No (N)'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T16:56:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a5ae45cb-942e-4a12-b5d3-8571390a4eb4'	System	03 Aug 2020 21:56:56
User entered '03 Aug 2020 16:56'	System	03 Aug 2020 21:56:56

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 16:39'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 19:09'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'None (0)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:21', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'None (0)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'None (0)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'None (0)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'None (0)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'None (0)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered 'No (N)'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-03T21:41:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f2e099b-6b61-44c6-9970-5db06fd1bb5b'	System	04 Aug 2020 02:41:40
User entered '03 Aug 2020 21:41'	System	04 Aug 2020 02:41:40

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '03 Aug 2020 20:04'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 2'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'None (0)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'Some interference with activity (2)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'Some interference with activity (2)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'None (0)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:27:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:28:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'None (0)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:28:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered 'No (N)'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-04T16:28:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f82e9e77-3b99-4cfe-9126-009c47244986'	System	04 Aug 2020 21:28:24
User entered '04 Aug 2020 16:28'	System	04 Aug 2020 21:28:24

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 3'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'None (0)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'None (0)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'None (0)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'None (0)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'None (0)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'None (0)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered 'No (N)'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-05T17:39:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c6897fd3-4b5a-4253-b647-7cae5722dfd8'	System	05 Aug 2020 22:39:58
User entered '05 Aug 2020 17:39'	System	05 Aug 2020 22:39:58

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 4'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:03', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'None (0)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'None (0)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'None (0)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'None (0)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'None (0)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'None (0)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered 'No (N)'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-06T14:50:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '8e66ce12-becb-4e7b-8083-98dc03711edc'	System	06 Aug 2020 19:50:48
User entered '06 Aug 2020 14:50'	System	06 Aug 2020 19:50:48

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 5'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'None (0)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:16', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'None (0)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'None (0)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'None (0)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'None (0)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'None (0)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered 'No (N)'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-07T18:09:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5c1eb005-393d-4c3a-8418-4ca9931357be'	System	07 Aug 2020 23:09:34
User entered '07 Aug 2020 18:09'	System	07 Aug 2020 23:09:34

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 6'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'None (0)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:16', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'None (0)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'None (0)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'None (0)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:21', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'None (0)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'None (0)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3cfbfada-0cb0-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered 'No (N)'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-08T18:06:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3c55ecb2fb8fae2a-4057-8b48-66ba228a3486'	System	08 Aug 2020 23:06:32
User entered '08 Aug 2020 18:06'	System	08 Aug 2020 23:06:32

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 7'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'None (0)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'None (0)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'None (0)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'None (0)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'None (0)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:21', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'None (0)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered 'No (N)'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-08-09T12:49:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '83bd688a-206a-47ca-b033-5af1f315f1e1'	System	09 Aug 2020 17:49:31
User entered '09 Aug 2020 12:49'	System	09 Aug 2020 17:49:31

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 21:21:20

US3212013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:12:09

US3212013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '10 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 20:12:09

US3212013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	18 Aug 2020 20:12:09

US3212013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 20:12:09

US3212013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:12:12

US3212013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	18 Aug 2020 20:12:12

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	18 Aug 2020 20:12:21

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '17 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 20:12:21

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Heather Leary (b) (4)	18 Aug 2020 20:12:21

US3212013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 20:12:21

US3212013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 14:22:44

US3212013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	25 Aug 2020 14:22:44

US3212013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Swab sample with a Collection date of 31AUG2020, however this data is missing in EDC. Please clarify if the Unscheduled sample with a Collection Date of 31AUG2020 was collected, and if so, please update the COVID-19 Assessments Folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:55:33
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Swab sample with a Collection date of 31AUG2020, however this data is missing in EDC. Please clarify if the Unscheduled sample with a Collection Date of 31AUG2020 was collected, and if so, please update the COVID-19 Assessments Folder, as appropriate.' answered with 'A SWAB WAS COLLECTED ON 31AUG2020 AT VISIT 2' (Site from DM).	Heather Leary (b) (4)	13 Jan 2021 17:27:53
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Swab sample with a Collection date of 31AUG2020, however this data is missing in EDC. Please clarify if the Unscheduled sample with a Collection Date of 31AUG2020 was collected, and if so, please update the COVID-19 Assessments Folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 18:04:31
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 14:22:57

US3212013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '24 Aug 2020'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 14:22:57

US3212013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 14:22:57

US3212013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 14:22:57

US3212013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	25 Aug 2020 14:23:05

US3212013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	25 Aug 2020 14:23:05

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Sep 2020 17:13:23

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 08:56:52
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'dates correct as entered' (Site from System).	Reagan Reed (b) (4)	09 Dec 2020 21:40:56
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Dec 2020 16:33:48
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:33:48
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 16:03:45
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'illness visit occurred' (Site from System).	Afifah Ayub (b) (4)	07 Oct 2020 20:53:42
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Oct 2020 20:53:27
User entered '7 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:53:27
User entered '31 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	02 Sep 2020 17:14:40
User entered '2 Sep 2020'	Afifah Ayub (b) (4)	02 Sep 2020 17:13:23

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	02 Sep 2020 17:13:23

US3212013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'VISIT2'	System	02 Sep 2020 17:13:23

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou	09 Sep 2020 14:37:17
	(b) (4)	

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:33:55
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:57:01
User entered '7 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:53:27
User entered '31 Aug 2020'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14:58' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01
User entered '16:13'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered '07 Oct 2020 14:58'	System	07 Dec 2020 16:33:55
User entered '7 Oct 2020 14:58'	System	07 Oct 2020 20:57:01
User entered '31 Aug 2020 16:13'	System	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '97.5' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01
User entered '98.4' F	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '88' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01
User entered '83'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'bpm'	System	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01
User entered '17'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'breaths/min'	System	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '124' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01
User entered '135'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'mmHg'	System	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '88'	Laura Ngansop Djampou (b) (4)	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'mmHg'	System	09 Sep 2020 14:37:17

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 20:03:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 20:03:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:03:10
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:57:47
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:47
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:57:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 20:57:20
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:57:20
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 20:57:01
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '07 Oct 2020' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '16:28' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered '07 Oct 2020 16:28'	System	13 Oct 2020 20:03:10
User entered empty.	System	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 20:04:13
User entered '98.2' F reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:04:13
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 20:04:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:04:22
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:13
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 20:04:13
User entered '75' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:04:13
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'bpm'	System	13 Oct 2020 20:04:13
User entered empty.	System	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 20:04:13
User entered '16' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:04:13
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'breaths/min'	System	13 Oct 2020 20:04:13
User entered empty.	System	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 20:04:13
User entered '132' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:04:13
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'mmHg'	System	13 Oct 2020 20:04:13
User entered empty.	System	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:04:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).		13 Oct 2020 20:04:13
User entered '88' reason for change: Data Entry Error	Anna Pena (b) (4)	13 Oct 2020 20:04:13
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:03:10
User entered empty.	Afifah Ayub (b) (4)	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'mmHg'	System	13 Oct 2020 20:04:13
User entered empty.	System	07 Oct 2020 20:57:01

US3212013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Sep 2020 17:14:00

US3212013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:34:00
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:54:11
User entered '7 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:54:11
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:53:27
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:14:40
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:14:27
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:14:27
User entered '31 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	02 Sep 2020 17:14:27
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:14:00
User entered '1 Sep 2020'	Afifah Ayub (b) (4)	02 Sep 2020 17:14:00

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4)	07 Oct 2020 20:50:29
User entered 'No (N)'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change New Information	Heather Leary (b) (4)	07 Oct 2020 20:50:29
User entered 'Protocol Deviation (PROTOCOL DEVIATION)'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	07 Oct 2020 20:50:29
User entered 'Subject received blood transfusions -prohibited as per protocol'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 20:50:29
User entered empty.	System	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '07 Oct 2020' reason for change: New Information	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:34:07
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:17:45
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. answered with 'AEs updated for dose delayed' (Site from DM).	Heather Leary (b) (4)	20 Oct 2020 21:12:44
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 18:39:39
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 09:35:04
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Dose was delayed due to blood transfusion, PI approved dosage for this date' (Site from System).	Heather Leary (b) (4)	07 Oct 2020 20:50:47
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:50:29
User entered '7 Oct 2020' reason for change: New Information	Heather Leary (b) (4)	07 Oct 2020 20:50:29
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15:43' reason for change: New Information	Heather Leary (b) (4)	07 Oct 2020 20:50:29
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered '07 Oct 2020 15:43'	System	07 Dec 2020 16:34:07
User entered '7 Oct 2020 15:43'	System	07 Oct 2020 20:50:29
User entered empty.	System	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Left Arm (LEFT ARM)' reason for change: New Information	Heather Leary (b) (4)	07 Oct 2020 20:50:29
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'ONCE'	System	07 Oct 2020 20:50:29
User entered empty.	System	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:44:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 20:50:29
User entered empty.	System	02 Sep 2020 17:15:12

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:31

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per GCL Lab Reconciliation: Immunogenicity: Sample dated 07OCT2020 collected for Visit 2 Day 29 visit in EDC is reported under Unscheduled [1] visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity: Sample dated 07OCT2020 collected for Visit 2 Day 29 visit in EDC is reported under Unscheduled [1] visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Sample dated 07OCT2020 collected for Visit 2 Day 29 visit. Query resolved in PPD Preclarus Portal' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:58:30
Query 'Per GCL Lab Reconciliation: Immunogenicity: Sample dated 07OCT2020 collected for Visit 2 Day 29 visit in EDC is reported under Unscheduled [1] visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Sample dated 07OCT2020 collected for Visit 2 Day 29 visit. Query resolved in PPD Preclarus Portal' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 22:12:41
User entered '07 Oct 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	11 Nov 2020 21:45:13
User opened query 'Per GCL Lab Reconciliation: Immunogenicity: Sample dated 07OCT2020 collected for Visit 2 Day 29 visit in EDC is reported under Unscheduled [1] visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:42:26
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit2 Day29 in EDC, however the same is reported under Visit2 Day29 with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:42:05

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit2 Day29 in EDC, however the same is reported under Visit2 Day29 with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' answered with 'The data entered is correct.' (Site from DM).	Afifah Ayub (b) (4)	28 Oct 2020 21:17:49
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit2 Day29 in EDC, however the same is reported under Visit2 Day29 with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:03:46
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:55:04
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		07 Oct 2020 20:55:04
User entered '7 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:55:04
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:53:27
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:31

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15:25' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:56:02
User entered '15:20' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:55:34
User entered '15:25' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:55:18
User entered '16:40'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:31

US3212013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered '07 Oct 2020 15:25'	System	11 Nov 2020 21:45:13
User entered '7 Oct 2020 15:25'	System	07 Oct 2020 20:56:02
User entered '7 Oct 2020 15:20'	System	07 Oct 2020 20:55:34
User entered '7 Oct 2020 15:25'	System	07 Oct 2020 20:55:18
User entered '7 Oct 2020 16:40'	System	07 Oct 2020 20:55:04
User entered '31 Aug 2020 16:40'	System	02 Sep 2020 17:15:31

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '07 Oct 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:34:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 09:38:48
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'An unscheduled visit was done to collect NP swab. Please clarify your query.' (Site from DM).	Reagan Reed (b) (4)	06 Nov 2020 15:02:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 04:51:45
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 07OCT2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Visit2 Day29 Visit with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:41:59

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 07OCT2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Visit2 Day29 Visit with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'The data entered is correct.' (Site from DM).	Afifah Ayub (b) (4)	28 Oct 2020 21:15:38
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 07OCT2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Visit2 Day29 Visit with date 31AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:46:10
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:55:53
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		07 Oct 2020 20:55:53
User entered '7 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:55:53
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 20:53:27
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15:20' reason for change: Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 20:55:53
User entered '16:35'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:44:16

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' canceled (Site from DM). User entered '07 Oct 2020 15:20'	(b) (4), (b) (6)	26 Mar 2021 12:18:12
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM). User entered '7 Oct 2020 15:20'	System	07 Dec 2020 16:34:18
User entered '31 Aug 2020 16:35'	(b) (4), (b) (6)	27 Nov 2020 09:39:19
	System	07 Oct 2020 20:55:53
	System	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered empty.	System	02 Sep 2020 17:15:48

US3212013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:13:28
User entered 'No (N)'	Afifah Ayub (b) (4)	02 Sep 2020 17:16:03

US3212013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered '1'	System	14 Sep 2020 16:13:28
User entered empty.	System	02 Sep 2020 17:16:03

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e'	System	07 Oct 2020 21:20:47
User entered 'Yes (Y)'	System	07 Oct 2020 21:20:47

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e'	System	07 Oct 2020 21:20:47
User entered '98.2'	System	07 Oct 2020 21:20:47

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e'	System	07 Oct 2020 21:20:47
User entered 'No (N)'	System	07 Oct 2020 21:20:47

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:20:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a6e6855d-0c75-4778-927d-025f45983d4e'	System	07 Oct 2020 21:20:47
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 21:20:47

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 16:03'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 18:33'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:19:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a'	System	08 Oct 2020 03:20:24
User entered 'Yes (Y)'	System	08 Oct 2020 03:20:24

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a'	System	08 Oct 2020 03:20:24
User entered '99.1'	System	08 Oct 2020 03:20:24

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a'	System	08 Oct 2020 03:20:24
User entered 'No (N)'	System	08 Oct 2020 03:20:24

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '4c394eb7-920a-4f31-9325-4e0b25bbb83a'	System	08 Oct 2020 03:20:24
User entered '07 Oct 2020 22:20'	System	08 Oct 2020 03:20:24

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 19:28'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 2'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:55:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c'	System	08 Oct 2020 18:56:45
User entered 'Yes (Y)'	System	08 Oct 2020 18:56:45

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c' User entered '98.3'	System	08 Oct 2020 18:56:45
	System	08 Oct 2020 18:56:45

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c'	System	08 Oct 2020 18:56:45
User entered 'No (N)'	System	08 Oct 2020 18:56:45

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5551d8aa-1150-4708-83ce-7eea5df2651c'	System	08 Oct 2020 18:56:45
User entered '08 Oct 2020 13:56'	System	08 Oct 2020 18:56:45

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 3'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e'	System	10 Oct 2020 03:21:42
User entered 'Yes (Y)'	System	10 Oct 2020 03:21:42

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e'	System	10 Oct 2020 03:21:42
User entered '98.9'	System	10 Oct 2020 03:21:42

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e'	System	10 Oct 2020 03:21:42
User entered 'No (N)'	System	10 Oct 2020 03:21:42

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cf7f884a-b6c4-48fa-b598-efb05488928e'	System	10 Oct 2020 03:21:42
User entered '09 Oct 2020 22:21'	System	10 Oct 2020 03:21:42

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 4'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7'	System	10 Oct 2020 23:20:07
User entered 'Yes (Y)'	System	10 Oct 2020 23:20:07

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7'	System	10 Oct 2020 23:20:07
User entered '98.9'	System	10 Oct 2020 23:20:07

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7'	System	10 Oct 2020 23:20:07
User entered 'No (N)'	System	10 Oct 2020 23:20:07

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:20:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f0d82a2d-132e-4cd1-bb82-e6b07f30e7f7'	System	10 Oct 2020 23:20:07
User entered '10 Oct 2020 18:20'	System	10 Oct 2020 23:20:07

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 5'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-11T23:59:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9'	System	12 Oct 2020 05:00:08
User entered 'Yes (Y)'	System	12 Oct 2020 05:00:08

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-11T23:59:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9'	System	12 Oct 2020 05:00:08
User entered '98.9'	System	12 Oct 2020 05:00:08

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-11T23:59:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9'	System	12 Oct 2020 05:00:08
User entered 'No (N)'	System	12 Oct 2020 05:00:08

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '2632df7a-0bb3-458f-859c-7c58a0577ba9'	System	12 Oct 2020 05:00:08
User entered '12 Oct 2020 00:00'	System	12 Oct 2020 05:00:08

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 6'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780'	System	13 Oct 2020 05:47:48
User entered 'Yes (Y)'	System	13 Oct 2020 05:47:48

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780'	System	13 Oct 2020 05:47:48
User entered '99.0'	System	13 Oct 2020 05:47:48

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780'	System	13 Oct 2020 05:47:48
User entered 'No (N)'	System	13 Oct 2020 05:47:48

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1011891b-5841-4f10-bb62-ef55f6c15780'	System	13 Oct 2020 05:47:48
User entered '13 Oct 2020 00:47'	System	13 Oct 2020 05:47:48

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 7'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:27:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0'	System	14 Oct 2020 03:28:22
User entered 'Yes (Y)'	System	14 Oct 2020 03:28:22

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0' User entered '98.7'	System	14 Oct 2020 03:28:22
	System	14 Oct 2020 03:28:22

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0'	System	14 Oct 2020 03:28:22
User entered 'No (N)'	System	14 Oct 2020 03:28:22

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5cac6af6-8f47-4862-a300-172749f067f0'	System	14 Oct 2020 03:28:22
User entered '13 Oct 2020 22:28'	System	14 Oct 2020 03:28:22

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:09', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17'	System	07 Oct 2020 21:21:22
User entered 'None (1)'	System	07 Oct 2020 21:21:22

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:13', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17'	System	07 Oct 2020 21:21:22
User entered 'No (N)'	System	07 Oct 2020 21:21:22

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17'	System	07 Oct 2020 21:21:22
User entered 'No (N)'	System	07 Oct 2020 21:21:22

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17'	System	07 Oct 2020 21:21:22
User entered 'None (1)'	System	07 Oct 2020 21:21:22

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b6241cab-cf32-40b2-ad8b-9b5e8603cf17'	System	07 Oct 2020 21:21:22
User entered '07 Oct 2020 16:21'	System	07 Oct 2020 21:21:22

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 16:03'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 18:33'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:20:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be'	System	08 Oct 2020 03:21:26
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 03:21:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be'	System	08 Oct 2020 03:21:26
User entered 'No (N)'	System	08 Oct 2020 03:21:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be'	System	08 Oct 2020 03:21:26
User entered 'No (N)'	System	08 Oct 2020 03:21:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be'	System	08 Oct 2020 03:21:26
User entered 'None (1)'	System	08 Oct 2020 03:21:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5093a860-4ef0-4fc9-a21a-3bff204409be'	System	08 Oct 2020 03:21:26
User entered '07 Oct 2020 22:21'	System	08 Oct 2020 03:21:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 19:28'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 2'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:56:55', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588'	System	08 Oct 2020 18:57:26
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 18:57:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588'	System	08 Oct 2020 18:57:26
User entered 'No (N)'	System	08 Oct 2020 18:57:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588'	System	08 Oct 2020 18:57:26
User entered 'No (N)'	System	08 Oct 2020 18:57:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588'	System	08 Oct 2020 18:57:26
User entered 'None (1)'	System	08 Oct 2020 18:57:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'b13e3335-9d82-4ba7-878a-7759a63aa588'	System	08 Oct 2020 18:57:26
User entered '08 Oct 2020 13:57'	System	08 Oct 2020 18:57:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 3'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:20:52', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d'	System	10 Oct 2020 03:21:07
User entered 'None (1)'	System	10 Oct 2020 03:21:07

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:20:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d'	System	10 Oct 2020 03:21:07
User entered 'No (N)'	System	10 Oct 2020 03:21:07

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:20:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d'	System	10 Oct 2020 03:21:07
User entered 'No (N)'	System	10 Oct 2020 03:21:07

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d'	System	10 Oct 2020 03:21:07
User entered 'None (1)'	System	10 Oct 2020 03:21:07

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '69ea5957-3f21-4cdd-abbf-5c61ba8b110d' User entered '09 Oct 2020 22:21'	System	10 Oct 2020 03:21:07
	System	10 Oct 2020 03:21:07

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 4'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324'	System	10 Oct 2020 23:19:26
User entered 'None (1)'	System	10 Oct 2020 23:19:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324'	System	10 Oct 2020 23:19:26
User entered 'No (N)'	System	10 Oct 2020 23:19:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:19', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324'	System	10 Oct 2020 23:19:26
User entered 'No (N)'	System	10 Oct 2020 23:19:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324'	System	10 Oct 2020 23:19:26
User entered 'None (1)'	System	10 Oct 2020 23:19:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c5552a9c-b976-4974-b3a6-333fe7ca9324'	System	10 Oct 2020 23:19:26
User entered '10 Oct 2020 18:19'	System	10 Oct 2020 23:19:26

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 5'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:08', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b'	System	12 Oct 2020 05:00:21
User entered 'None (1)'	System	12 Oct 2020 05:00:21

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:11', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b'	System	12 Oct 2020 05:00:21
User entered 'No (N)'	System	12 Oct 2020 05:00:21

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:13', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b'	System	12 Oct 2020 05:00:21
User entered 'No (N)'	System	12 Oct 2020 05:00:21

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b'	System	12 Oct 2020 05:00:21
User entered 'None (1)'	System	12 Oct 2020 05:00:21

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '91631990-62ae-431a-9bc8-a7aa7128be6b'	System	12 Oct 2020 05:00:21
User entered '12 Oct 2020 00:00'	System	12 Oct 2020 05:00:21

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 6'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427'	System	13 Oct 2020 05:48:31
User entered 'None (1)'	System	13 Oct 2020 05:48:31

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:47:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427'	System	13 Oct 2020 05:48:31
User entered 'No (N)'	System	13 Oct 2020 05:48:31

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427'	System	13 Oct 2020 05:48:31
User entered 'No (N)'	System	13 Oct 2020 05:48:31

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:02', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427'	System	13 Oct 2020 05:48:31
User entered 'None (1)'	System	13 Oct 2020 05:48:31

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '64df016b-0cab-40b1-8d65-4a9c0a5b7427'	System	13 Oct 2020 05:48:31
User entered '13 Oct 2020 00:48'	System	13 Oct 2020 05:48:31

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 7'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3'	System	14 Oct 2020 03:28:41
User entered 'None (1)'	System	14 Oct 2020 03:28:41

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3'	System	14 Oct 2020 03:28:41
User entered 'No (N)'	System	14 Oct 2020 03:28:41

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3'	System	14 Oct 2020 03:28:41
User entered 'No (N)'	System	14 Oct 2020 03:28:41

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3'	System	14 Oct 2020 03:28:41
User entered 'None (1)'	System	14 Oct 2020 03:28:41

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '51c07fec-033b-4021-853e-1f89c1d2baf3'	System	14 Oct 2020 03:28:41
User entered '13 Oct 2020 22:28'	System	14 Oct 2020 03:28:41

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1'	System	07 Oct 2020 21:21:41
User entered 'None (0)'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1'	System	07 Oct 2020 21:21:41
User entered 'None (0)'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' User entered 'None (0)'	System	07 Oct 2020 21:21:41
	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1' User entered 'None (0)'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1'	System	07 Oct 2020 21:21:41
User entered 'None (0)'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1'	System	07 Oct 2020 21:21:41
User entered 'None (0)'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1'	System	07 Oct 2020 21:21:41
User entered 'No (N)'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T16:21:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '24495028-1aa1-4f68-98ba-fa3dbb2393f1'	System	07 Oct 2020 21:21:41
User entered '07 Oct 2020 16:21'	System	07 Oct 2020 21:21:41

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 16:03'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 18:33'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'None (0)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'No interference with activity (1)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'No interference with activity (1)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'None (0)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:21:59', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'None (0)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:22:01', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'None (0)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:22:04', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered 'No (N)'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T22:22:06', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '168b8001-80d7-41b9-93c5-44d864b9d8c2'	System	08 Oct 2020 03:22:09
User entered '07 Oct 2020 22:22'	System	08 Oct 2020 03:22:09

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '07 Oct 2020 19:28'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 2'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'None (0)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'None (0)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'None (0)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'None (0)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'None (0)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'None (0)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered 'No (N)'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-08T13:57:46', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '78184763-6b06-4c13-b2a4-0ca6b297aea6'	System	08 Oct 2020 18:57:48
User entered '08 Oct 2020 13:57'	System	08 Oct 2020 18:57:48

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 3'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'None (0)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:07', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'None (0)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:09', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'None (0)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'None (0)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'None (0)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:13', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'None (0)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered 'No (N)'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-09T22:21:17', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '5703e3a0-d870-4234-9e70-9269d12e8572'	System	10 Oct 2020 03:21:20
User entered '09 Oct 2020 22:21'	System	10 Oct 2020 03:21:20

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 4'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'None (0)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'None (0)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'None (0)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'None (0)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'None (0)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'None (0)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered 'No (N)'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T18:19:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'c8310d9f-6166-472b-92b3-a864ee3bfe76'	System	10 Oct 2020 23:19:43
User entered '10 Oct 2020 18:19'	System	10 Oct 2020 23:19:43

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 5'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:23', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'None (0)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:24', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'None (0)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'None (0)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'None (0)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'None (0)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'None (0)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered 'No (N)'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-12T00:00:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '9f73ad54-87e1-4166-9bca-ba125506dda2'	System	12 Oct 2020 05:00:37
User entered '12 Oct 2020 00:00'	System	12 Oct 2020 05:00:37

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 6'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'None (0)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:31', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'None (0)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:32', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'None (0)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'None (0)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'None (0)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:36', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'None (0)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:38', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered 'No (N)'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T00:48:40', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fb776db6-e295-401d-8cfd-56ef4b0f90ce'	System	13 Oct 2020 05:48:42
User entered '13 Oct 2020 00:48'	System	13 Oct 2020 05:48:42

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	07 Oct 2020 20:50:29
User entered 'Day 7'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:41', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'None (0)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:43', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'None (0)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'None (0)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'None (0)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:47', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'None (0)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'None (0)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:50', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered 'No (N)'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-13T22:28:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'dfdb8021-d82e-4485-a0ee-31f99a2dac2e'	System	14 Oct 2020 03:28:59
User entered '13 Oct 2020 22:28'	System	14 Oct 2020 03:28:59

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 20:50:29

US3212013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:44:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 20:50:29

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:23:25

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 16:08:28
User entered '15 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	16 Oct 2020 20:27:54
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'dose was delayed due to subject receiving blood transfusion; safety calls after dosing will be captured as unscheduled visits' (Site from System).	Heather Leary (b) (4)	07 Oct 2020 21:47:31
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 20:50:29
User entered '8 Sep 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:23:25

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:23:25

US3212013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:23:25

US3212013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:23:37

US3212013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	14 Sep 2020 16:23:37

US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 13:41:56

US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '21 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	22 Oct 2020 17:10:19
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), (b) (6)	19 Oct 2020 16:08:35
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 with 'IP was withheld at V2 due to blood transfusion; PI permitted IP administration at later date (7Oct2020)' (Site from System).	Heather Leary (b) (4)	08 Oct 2020 16:28:23
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	07 Oct 2020 20:50:29
User entered '15 Sep 2020'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 13:41:56

US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 13:41:56

US3212013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	16 Sep 2020 13:41:56

US3212013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Sep 2020 13:42:02

US3212013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	16 Sep 2020 13:42:02

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 20:17:40

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '28 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Oct 2020 20:32:44
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 16:08:38
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'IP was not administered at initial V2 due to subject receiving blood transfusion; PI authorized administration of IP on 7Oct2020' (Site from System).	Heather Leary (b) (4)	08 Oct 2020 16:29:59
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 20:50:29
User entered '21 Sep 2020'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 20:17:40

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 20:17:40

US3212013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	01 Oct 2020 20:17:40

US3212013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 20:17:46

US3212013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	01 Oct 2020 20:17:46

US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:04

US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '04 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:33:33
User entered '4 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:04

US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:04

US3212013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'VISIT3'	System	04 Nov 2020 21:35:04

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '04 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:33:25
User entered '4 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14:24'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered '04 Nov 2020 14:24'	System	07 Dec 2020 16:33:25
User entered '4 Nov 2020 14:24'	System	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '97.2' F	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '80'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'bpm'	System	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '18'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'breaths/min'	System	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '102'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'mmHg'	System	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '79'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'mmHg'	System	04 Nov 2020 21:36:01

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55

US3212013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55

US3212013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:14

US3212013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '04 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:33:17
User entered '4 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:14

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:28

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '04 Nov 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:33:06
User entered '4 Nov 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:28

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15:21'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:28

US3212013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered '04 Nov 2020 15:21'	System	07 Dec 2020 16:33:06
User entered '4 Nov 2020 15:21'	System	04 Nov 2020 21:35:28

US3212013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:35:34

US3212013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:55
User entered 'I'	System	04 Nov 2020 21:35:34

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 64'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db'	System	07 Oct 2020 19:32:06
User entered 'Yes (Y)'	System	07 Oct 2020 19:32:06

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db'	System	07 Oct 2020 19:32:06
User entered 'No (N)'	System	07 Oct 2020 19:32:06

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db'	System	07 Oct 2020 19:32:06
User entered 'No (N)'	System	07 Oct 2020 19:32:06

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:56', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db'	System	07 Oct 2020 19:32:06
User entered 'No (N)'	System	07 Oct 2020 19:32:06

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-07T14:31:59', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '27f33a8c-76eb-4660-84cd-2a7fe4d431db'	System	07 Oct 2020 19:32:06
User entered '07 Oct 2020 14:31:59'	System	07 Oct 2020 19:32:06

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 71'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T00:20:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0cbd153a-f2c7-4095-9159-8794c55a4be3'	System	10 Oct 2020 05:20:52
User entered 'No (N)'	System	10 Oct 2020 05:20:52

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T00:20:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0cbd153a-f2c7-4095-9159-8794c55a4be3'	System	10 Oct 2020 05:20:52
User entered 'No (N)'	System	10 Oct 2020 05:20:52

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-10T00:20:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '0cbd153a-f2c7-4095-9159-8794c55a4be3' User entered '10 Oct 2020 00:20:48'	System	10 Oct 2020 05:20:52
	System	10 Oct 2020 05:20:52

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 78'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-21T02:40:44', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cbd5ec10-9c5d-4d0a-9c43-f7129406bf12'	System	21 Oct 2020 07:40:57
User entered 'No (N)'	System	21 Oct 2020 07:40:57

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-21T02:40:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cbd5ec10-9c5d-4d0a-9c43-f7129406bf12'	System	21 Oct 2020 07:40:57
User entered 'No (N)'	System	21 Oct 2020 07:40:57

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-21T02:40:54', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'cbd5ec10-9c5d-4d0a-9c43-f7129406bf12'	System	21 Oct 2020 07:40:57
User entered '21 Oct 2020 02:40:54'	System	21 Oct 2020 07:40:57

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 92'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-31T17:15:22', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ecef065-ea63-4a9e-a863-12bff2c86db5'	System	31 Oct 2020 22:15:34
User entered 'No (N)'	System	31 Oct 2020 22:15:34

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-31T17:15:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ecef065-ea63-4a9e-a863-12bff2c86db5'	System	31 Oct 2020 22:15:34
User entered 'No (N)'	System	31 Oct 2020 22:15:34

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-10-31T17:15:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ecef065-ea63-4a9e-a863-12bff2c86db5'	System	31 Oct 2020 22:15:34
User entered '31 Oct 2020 17:15:30'	System	31 Oct 2020 22:15:34

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 99'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-07T00:48:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fe01dd26-1610-4eca-93ac-e2db6632da69'	System	07 Nov 2020 06:48:35
User entered 'No (N)'	System	07 Nov 2020 06:48:35

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-07T00:48:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fe01dd26-1610-4eca-93ac-e2db6632da69'	System	07 Nov 2020 06:48:35
User entered 'No (N)'	System	07 Nov 2020 06:48:35

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-07T00:48:32', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'fe01dd26-1610-4eca-93ac-e2db6632da69' User entered '07 Nov 2020 00:48:32'	System	07 Nov 2020 06:48:35
	System	07 Nov 2020 06:48:35

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered 'Day 106'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-14T00:32:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '126d04bb-11b6-40a2-b2a8-2571782e7a3d'	System	14 Nov 2020 06:32:14
User entered 'No (N)'	System	14 Nov 2020 06:32:14

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-14T00:32:07', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '126d04bb-11b6-40a2-b2a8-2571782e7a3d'	System	14 Nov 2020 06:32:14
User entered 'No (N)'	System	14 Nov 2020 06:32:14

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-14T00:32:09', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '126d04bb-11b6-40a2-b2a8-2571782e7a3d'	System	14 Nov 2020 06:32:14
User entered '14 Nov 2020 00:32:09'	System	14 Nov 2020 06:32:14

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 21:21:20

US3212013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:02:05
Data entry locked.	System	03 Aug 2020 21:21:20
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 21:21:20

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-28T19:14:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a4bd0487-9c11-4664-9fb6-3db6196556c6'	System	29 Nov 2020 01:14:47
User entered 'No (N)'	System	29 Nov 2020 01:14:47

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-28T19:14:42', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a4bd0487-9c11-4664-9fb6-3db6196556c6'	System	29 Nov 2020 01:14:47
User entered 'No (N)'	System	29 Nov 2020 01:14:47

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-11-28T19:14:45', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a4bd0487-9c11-4664-9fb6-3db6196556c6'	System	29 Nov 2020 01:14:47
User entered '28 Nov 2020 19:14:45'	System	29 Nov 2020 01:14:47

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-05T17:59:48', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '751a2d59-d99c-431b-b9b8-070ec6f0bd87'	System	05 Dec 2020 23:59:54
User entered 'No (N)'	System	05 Dec 2020 23:59:54

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-05T17:59:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '751a2d59-d99c-431b-b9b8-070ec6f0bd87'	System	05 Dec 2020 23:59:54
User entered 'No (N)'	System	05 Dec 2020 23:59:54

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-05T17:59:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '751a2d59-d99c-431b-b9b8-070ec6f0bd87'	System	05 Dec 2020 23:59:54
User entered '05 Dec 2020 17:59:51'	System	05 Dec 2020 23:59:54

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-09T00:01:25', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '13ab7d10-b2a2-41bd-bdfe-94e57420631c'	System	09 Dec 2020 06:01:43
User entered 'No (N)'	System	09 Dec 2020 06:01:43

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-09T00:01:27', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '13ab7d10-b2a2-41bd-bdfe-94e57420631c'	System	09 Dec 2020 06:01:43
User entered 'No (N)'	System	09 Dec 2020 06:01:43

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-09T00:01:29', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '13ab7d10-b2a2-41bd-bdfe-94e57420631c'	System	09 Dec 2020 06:01:43
User entered '09 Dec 2020 00:01:29'	System	09 Dec 2020 06:01:43

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-17T13:39:26', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f5c13f2-68da-4f9d-8d47-da0d40e1be72'	System	17 Dec 2020 19:39:37
User entered 'No (N)'	System	17 Dec 2020 19:39:37

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-17T13:39:28', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f5c13f2-68da-4f9d-8d47-da0d40e1be72'	System	17 Dec 2020 19:39:37
User entered 'No (N)'	System	17 Dec 2020 19:39:37

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-17T13:39:30', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '1f5c13f2-68da-4f9d-8d47-da0d40e1be72'	System	17 Dec 2020 19:39:37
User entered '17 Dec 2020 13:39:30'	System	17 Dec 2020 19:39:37

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-23T01:45:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'eb6eba27-367a-40bd-9e1f-29686fad9b75'	System	23 Dec 2020 07:45:45
User entered 'No (N)'	System	23 Dec 2020 07:45:45

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-23T01:45:34', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'eb6eba27-367a-40bd-9e1f-29686fad9b75'	System	23 Dec 2020 07:45:45
User entered 'No (N)'	System	23 Dec 2020 07:45:45

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-23T01:45:39', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'eb6eba27-367a-40bd-9e1f-29686fad9b75'	System	23 Dec 2020 07:45:45
User entered '23 Dec 2020 01:45:39'	System	23 Dec 2020 07:45:45

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-30T01:14:57', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ec4e7226-0f75-4434-a8c4-a426b566032e'	System	30 Dec 2020 07:15:06
User entered 'No (N)'	System	30 Dec 2020 07:15:06

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-30T01:14:58', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ec4e7226-0f75-4434-a8c4-a426b566032e'	System	30 Dec 2020 07:15:06
User entered 'No (N)'	System	30 Dec 2020 07:15:06

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2020-12-30T01:15:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'ec4e7226-0f75-4434-a8c4-a426b566032e'	System	30 Dec 2020 07:15:06
User entered '30 Dec 2020 01:15:00'	System	30 Dec 2020 07:15:06

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-08T11:07:47', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '827c57a9-9e35-441f-8cdc-b4e0e7c74012'	System	08 Jan 2021 17:07:55
User entered 'No (N)'	System	08 Jan 2021 17:07:55

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-08T11:07:49', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '827c57a9-9e35-441f-8cdc-b4e0e7c74012'	System	08 Jan 2021 17:07:55
User entered 'No (N)'	System	08 Jan 2021 17:07:55

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-08T11:07:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '827c57a9-9e35-441f-8cdc-b4e0e7c74012'	System	08 Jan 2021 17:07:55
User entered '08 Jan 2021 11:07:51'	System	08 Jan 2021 17:07:55

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-13T00:06:47', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '7c8ea996-59d4-452f-a8e1-8384de43440b'	System	13 Jan 2021 06:06:58
User entered 'No (N)'	System	13 Jan 2021 06:06:58

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-13T00:06:51', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '7c8ea996-59d4-452f-a8e1-8384de43440b'	System	13 Jan 2021 06:06:58
User entered 'No (N)'	System	13 Jan 2021 06:06:58

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-13T00:06:53', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '7c8ea996-59d4-452f-a8e1-8384de43440b' User entered '13 Jan 2021 00:06:53'	System	13 Jan 2021 06:06:58
	System	13 Jan 2021 06:06:58

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-24T15:33:15', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a71870f7-13b9-4b12-a1cb-a2d829b61203'	System	24 Jan 2021 21:33:25
User entered 'No (N)'	System	24 Jan 2021 21:33:25

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-24T15:33:18', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a71870f7-13b9-4b12-a1cb-a2d829b61203'	System	24 Jan 2021 21:33:25
User entered 'No (N)'	System	24 Jan 2021 21:33:25

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-24T15:33:20', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'a71870f7-13b9-4b12-a1cb-a2d829b61203'	System	24 Jan 2021 21:33:25
User entered '24 Jan 2021 15:33:20'	System	24 Jan 2021 21:33:25

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-27T00:01:33', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3993e17d-1052-49f0-ae5a-17f0487e7151'	System	27 Jan 2021 06:01:48
User entered 'No (N)'	System	27 Jan 2021 06:01:48

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-27T00:01:35', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3993e17d-1052-49f0-ae5a-17f0487e7151'	System	27 Jan 2021 06:01:48
User entered 'No (N)'	System	27 Jan 2021 06:01:48

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-01-27T00:01:37', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '3993e17d-1052-49f0-ae5a-17f0487e7151' User entered '27 Jan 2021 00:01:37'	System	27 Jan 2021 06:01:48
	System	27 Jan 2021 06:01:48

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-03T00:03:05', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '033c541f-96d7-4717-a160-3c620ddde15e'	System	03 Feb 2021 06:03:15
User entered 'No (N)'	System	03 Feb 2021 06:03:15

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-03T00:03:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '033c541f-96d7-4717-a160-3c620ddde15e'	System	03 Feb 2021 06:03:15
User entered 'No (N)'	System	03 Feb 2021 06:03:15

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-03T00:03:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '033c541f-96d7-4717-a160-3c620ddde15e'	System	03 Feb 2021 06:03:15
User entered '03 Feb 2021 00:03:12'	System	03 Feb 2021 06:03:15

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-20T14:19:10', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'e45a78d2-07d5-437c-a48d-77d61dde94de'	System	20 Feb 2021 20:19:20
User entered 'No (N)'	System	20 Feb 2021 20:19:20

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-20T14:19:12', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'e45a78d2-07d5-437c-a48d-77d61dde94de'	System	20 Feb 2021 20:19:20
User entered 'No (N)'	System	20 Feb 2021 20:19:20

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-20T14:19:14', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'e45a78d2-07d5-437c-a48d-77d61dde94de'	System	20 Feb 2021 20:19:20
User entered '20 Feb 2021 14:19:14'	System	20 Feb 2021 20:19:20

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-24T00:42:53-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'df047a10-9211-43e9-8190-9963aca3bb38'	System	24 Feb 2021 06:43:02
User entered 'No (N)'	System	24 Feb 2021 06:43:02

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-24T00:42:54-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'df047a10-9211-43e9-8190-9963aca3bb38'	System	24 Feb 2021 06:43:02
User entered 'No (N)'	System	24 Feb 2021 06:43:02

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-02-24T00:42:59-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'df047a10-9211-43e9-8190-9963aca3bb38' User entered '24 Feb 2021 00:42:59'	System	24 Feb 2021 06:43:02
	System	24 Feb 2021 06:43:02

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-05T14:09:40-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '7fd350b8-53ed-44db-b847-c5080014afbd'	System	05 Mar 2021 20:09:49
User entered 'No (N)'	System	05 Mar 2021 20:09:49

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-05T14:09:42-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '7fd350b8-53ed-44db-b847-c5080014afbd'	System	05 Mar 2021 20:09:49
User entered 'No (N)'	System	05 Mar 2021 20:09:49

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-05T14:09:46-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '7fd350b8-53ed-44db-b847-c5080014afbd' User entered '05 Mar 2021 14:09:46'	System	05 Mar 2021 20:09:49
	System	05 Mar 2021 20:09:49

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-12T02:08:48-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '81388c09-0f93-42ff-9acd-a8242d85bcb7'	System	12 Mar 2021 08:08:55
User entered 'No (N)'	System	12 Mar 2021 08:08:55

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-12T02:08:49-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '81388c09-0f93-42ff-9acd-a8242d85bcb7'	System	12 Mar 2021 08:08:55
User entered 'No (N)'	System	12 Mar 2021 08:08:55

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-12T02:08:52-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '81388c09-0f93-42ff-9acd-a8242d85bcb7'	System	12 Mar 2021 08:08:55
User entered '12 Mar 2021 02:08:52'	System	12 Mar 2021 08:08:55

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-17T00:01:42-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '87b74a51-c2bb-409b-b7d4-c8fac6b62ba2'	System	17 Mar 2021 05:01:51
User entered 'No (N)'	System	17 Mar 2021 05:01:51

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-17T00:01:43-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '87b74a51-c2bb-409b-b7d4-c8fac6b62ba2'	System	17 Mar 2021 05:01:51
User entered 'No (N)'	System	17 Mar 2021 05:01:51

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-17T00:01:47-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '87b74a51-c2bb-409b-b7d4-c8fac6b62ba2' User entered '17 Mar 2021 00:01:47'	System	17 Mar 2021 05:01:51
	System	17 Mar 2021 05:01:51

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-04-03T01:45:12-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '89ed4677-7e95-4153-8212-dcaa1a8b2d03'	System	03 Apr 2021 06:45:24
User entered 'No (N)'	System	03 Apr 2021 06:45:24

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-04-03T01:45:14-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '89ed4677-7e95-4153-8212-dcaa1a8b2d03'	System	03 Apr 2021 06:45:24
User entered 'No (N)'	System	03 Apr 2021 06:45:24

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-04-03T01:45:16-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '89ed4677-7e95-4153-8212-dcaa1a8b2d03'	System	03 Apr 2021 06:45:24
User entered '03 Apr 2021 01:45:16'	System	03 Apr 2021 06:45:24

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-04-14T00:01:23-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '30fa2552-6272-461a-8ba7-229b45908be6'	System	14 Apr 2021 05:01:36
User entered 'No (N)'	System	14 Apr 2021 05:01:36

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-04-14T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '30fa2552-6272-461a-8ba7-229b45908be6'	System	14 Apr 2021 05:01:36
User entered 'No (N)'	System	14 Apr 2021 05:01:36

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-04-14T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: '30fa2552-6272-461a-8ba7-229b45908be6'	System	14 Apr 2021 05:01:36
User entered '14 Apr 2021 00:01:28'	System	14 Apr 2021 05:01:36

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-05-02T16:22:50-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f1a3e43b-5d59-4b4b-9a16-2345faed6948'	System	02 May 2021 21:23:02
User entered 'No (N)'	System	02 May 2021 21:23:02

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-05-02T16:22:51-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f1a3e43b-5d59-4b4b-9a16-2345faed6948'	System	02 May 2021 21:23:02
User entered 'No (N)'	System	02 May 2021 21:23:02

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-05-02T16:22:58-05:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'f1a3e43b-5d59-4b4b-9a16-2345faed6948'	System	02 May 2021 21:23:02
User entered '02 May 2021 16:22:58'	System	02 May 2021 21:23:02

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 12:03:44

US3212013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:44:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:03:44
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 12:03:44

US3212013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:38:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-05T14:09:51-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'deb0318c-a1df-4e40-917d-a4b20605c488'	System	05 Mar 2021 20:09:57
User entered 'No (N)'	System	05 Mar 2021 20:09:57

US3212013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:44:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:38:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c55ecb2fb8fae2a)', Time: '2021-03-05T14:09:54-06:00', User OID: 'PatientReportedOutcome (US3212013)', ODM File OID: 'deb0318c-a1df-4e40-917d-a4b20605c488' User entered '05 Mar 2021 14:09:54'	System	05 Mar 2021 20:09:57
	System	05 Mar 2021 20:09:57

US3212013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	03 Dec 2020 22:15:49
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:17

US3212013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 08:52:55
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'repeat swab needed please see PPD for records' (Site from DM).	Reagan Reed (b) (4)	09 Dec 2020 14:37:03
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:46:27
User entered '03 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 22:25:18
User entered '2 Dec 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	03 Dec 2020 22:15:49
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:17

US3212013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Heather Leary (b) (4)	03 Dec 2020 22:15:49
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:17

US3212013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:17

US3212013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:21

US3212013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:55:52
User entered 'I'	System	03 Dec 2020 15:06:21

US3212013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Jan 2021 21:05:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 13:19:31
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:30:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:29:30
Query 'Data is required. Please complete.' answered with 'Day 119 eCRF filled out due to error in source documentation. Day 119 safety call has not yet occurred.' (Site from System).	Heather Leary (b) (4)	03 Dec 2020 22:15:28
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 22:14:48
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Dec 2020 22:14:48
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	03 Dec 2020 22:14:48
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Dec 2020 22:14:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:39

US3212013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	07 Jan 2021 21:36:02
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	07 Jan 2021 21:36:02
User entered '05 Jan 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Jan 2021 21:36:02
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 21:05:09
User entered '02 Dec 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Jan 2021 21:05:09
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	07 Dec 2020 16:30:11
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	07 Dec 2020 16:30:11
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:30:11
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	07 Dec 2020 16:29:30

US3212013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '03 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:29:30
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	03 Dec 2020 22:14:42
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	03 Dec 2020 22:14:42
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4) (b) (4)	03 Dec 2020 22:14:42
User entered '02 Dec 2020' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:07:11
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	03 Dec 2020 15:06:39
User entered '2 Dec 2020'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:39

US3212013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Jan 2021 21:05:09
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:30:11
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Dec 2020 16:29:30
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	03 Dec 2020 22:14:42
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:39

US3212013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:06:39

US3212013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	03 Dec 2020 15:07:16

US3212013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User entered 'I'	System	03 Dec 2020 15:07:16

US3212013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Feb 2021 15:08:41
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:38:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 21:38:13
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	07 Jan 2021 21:38:13
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 14:35:23
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 14:35:23

US3212013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '03 Feb 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	04 Feb 2021 15:08:41
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 14:35:23

US3212013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou	04 Feb 2021 15:08:41
reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 14:35:23

US3212013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 14:35:23

US3212013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	11 Jan 2021 19:48:36

US3212013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User entered 'I'	System	11 Jan 2021 19:48:36

US3212013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Mar 2021 16:44:59
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:44
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:22

US3212013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '05 Mar 2021' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Mar 2021 16:44:59
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Feb 2021 17:07:44
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Feb 2021 17:07:44
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:44
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Feb 2021 17:07:22
User entered '18 Feb 2021'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:22

US3212013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	08 Mar 2021 16:44:59
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:44
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:22

US3212013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:44:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	19 Feb 2021 17:07:22

US3212013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	08 Mar 2021 16:45:09

US3212013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:07:22
User entered 'I'	System	08 Mar 2021 16:45:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 13:50:27

US3212013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '07 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 13:50:27

US3212013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Apr 2021 13:50:27

US3212013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered 'VISIT4'	System	08 Apr 2021 13:50:27

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '07 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '12:15'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered '07 Apr 2021 12:15'	System	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '97.5' F	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '65'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered 'bpm'	System	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '17'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered 'breaths/min'	System	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '125'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered 'mmHg'	System	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '85'	(b) (4), (b) (6)	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered 'mmHg'	System	08 Apr 2021 13:51:09

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31

US3212013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31

US3212013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 13:51:23

US3212013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '07 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 13:51:23

US3212013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 13:51:40

US3212013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '07 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 13:51:40

US3212013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered '12:49'	(b) (4), (b) (6)	08 Apr 2021 13:51:40

US3212013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered '07 Apr 2021 12:49'	System	08 Apr 2021 13:51:40

US3212013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User signature succeeded.	Vicki Miller (b) (4)	08 Apr 2021 18:44:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 13:51:48

US3212013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:44:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:31
User entered 'I'	System	08 Apr 2021 13:51:48

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:44:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:42
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:06

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:44:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:42
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered '14:50'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:06

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:44:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:42
User entered '31 Aug 2020 14:50'	System	01 Apr 2021 15:58:06

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:44:16

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:42
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:06

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:44:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:42
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:06

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'I'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User entered empty.	System	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:44:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:52
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:20

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 31-Aug-2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported as an "Unscheduled" Visit sample (Accession No: 1F621004502) in PPD Central lab, Preclarus Report. Please review and confirm the correct Visit Name and make updates in EDC and PPD Portal as appropriate. Else clarify, Thank you' (Site from DM). Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 31-Aug-2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported as an "Unscheduled" Visit sample (Accession No: 1F621004502) in PPD Central lab, Preclarus Report. Please review and confirm the correct Visit Name and make updates in EDC and PPD Portal as appropriate. Else clarify, Thank you' answered with 'visit was unscheduled for NP swab, as there is no eCRF to capture NP swab/covid test in unscheduled visit in EDC it is documented in the COVID test folder' (Site from DM).	Heather Leary (b) (4)	15 Apr 2021 15:03:12
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 31-Aug-2020 is recorded under Covid-19 Assessment visit in EDC, however the same is reported as an "Unscheduled" Visit sample (Accession No: 1F621004502) in PPD Central lab, Preclarus Report. Please review and confirm the correct Visit Name and make updates in EDC and PPD Portal as appropriate. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 06:02:31
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered empty.	Afifah Ayub (b) (4)	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:44:16

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:29:57
User entered '0'	System	01 Apr 2021 15:58:42

US3212013

Folder: Covid-19 Assessment 31 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:44:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:30:06
User signature succeeded.	Vicki Miller (b) (4)	01 Apr 2021 19:17:04
User entered 'No (N)'	Afifah Ayub (b) (4)	01 Apr 2021 15:58:11

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	03 Feb 2021 19:54:16

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '3 Feb 2021'	Heather Leary (b) (4)	03 Feb 2021 19:54:16

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Clinic (Clinic)'	Heather Leary (b) (4)	03 Feb 2021 19:54:16

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:44:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 19:54:16

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '3 Feb 2021'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	(b) (4), (b) (6)	22 Mar 2021 19:22:12
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:15:29

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Insiya Valika (b) (4)	25 Apr 2021 17:55:11
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:23:41
Query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. subject was unblinded under A6, please review and update blank field.' answered with 'done' (Site from DM).	Heather Leary (b) (4)	22 Apr 2021 13:19:13
Signature has been broken.	Heather Leary (b) (4)	22 Apr 2021 13:18:39
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Heather Leary (b) (4)	22 Apr 2021 13:18:39
User opened query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:23:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 19:22:12
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:15:29

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '3 Feb 2021'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mRNA-1273 (mRNA-1273)'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Heather Leary (b) (4)	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User entered empty.	System	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:44:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User entered empty.	System	03 Feb 2021 19:54:27

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	03 Feb 2021 19:54:40

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '3 Feb 2021'	Heather Leary (b) (4)	03 Feb 2021 19:54:40

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '11:56'	Heather Leary (b) (4)	03 Feb 2021 19:54:40

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User entered '3 Feb 2021 11:56'	System	03 Feb 2021 19:54:40

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	03 Feb 2021 19:54:48

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:16

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '3 Feb 2021'	Heather Leary (b) (4)	03 Feb 2021 19:54:48

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '11:52'	Heather Leary (b) (4)	03 Feb 2021 19:54:48

US3212013

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:44:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:06:51
User entered '3 Feb 2021 11:52'	System	03 Feb 2021 19:54:48

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:24
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per GCL Lab Reconciliation: Sample dated 07OCT2020 is recorded under Unscheduled visit reported in PPD Central lab; however this Unscheduled visit is not in EDC. Please review update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 19:35:11
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please confirm if sample collected on 31AUG2020 and update the Unscheduled visit form. thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:53:06
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please confirm if sample collected on 31AUG2020 and update the Unscheduled visit form. thank you.' answered with 'yes all samples collected on 31AUG2020' (Site from DM).	Reagan Reed (b) (4)	23 Nov 2020 21:14:19
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please confirm if sample collected on 31AUG2020 and update the Unscheduled visit form. thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:02:59
User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:02:59

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Visit Date](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' answered with 'samples collected and the subject noted she received 3 units of blood in a transfusion, her dose 2 was delayed. but the samples had been collected ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	18 Nov 2020 16:49:31
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 31AUG2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	18 Nov 2020 06:09:02
Query 'Per GCL Lab Reconciliation: Sample dated 07OCT2020 is recorded under Unscheduled visit reported in PPD Central lab; however this Unscheduled visit is not in EDC. Please review update as appropriate, else clarify.' answered with 'An unscheduled visit was done to collect NP swab. Please clarify your query.' (Site from DM).	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 15:01:32
User opened query 'Per GCL Lab Reconciliation: Sample dated 07OCT2020 is recorded under Unscheduled visit reported in PPD Central lab; however this Unscheduled visit is not in EDC. Please review update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	29 Oct 2020 18:26:20
User entered '29 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	12 Oct 2020 15:51:48

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:24
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	12 Oct 2020 15:51:48

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:24
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	12 Oct 2020 15:51:48

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:24
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0' reason for change: Data Entry Error	Afifah Ayub (b) (4)	12 Oct 2020 15:53:29
User entered '1'	Afifah Ayub (b) (4)	12 Oct 2020 15:51:48

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:24
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	12 Oct 2020 15:51:48

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '29 Sep 2020'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14:47'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User entered '29 Sep 2020 14:47'	System	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '97.3' F	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '83'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User entered 'bpm'	System	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User entered 'breaths/min'	System	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '126'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User entered 'mmHg'	System	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '84'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31
User entered 'mmHg'	System	12 Oct 2020 15:52:17

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:31

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:27

US3212013

Folder: Unscheduled 29 Sep 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '29 Sep 2020'	Afifah Ayub (b) (4)	12 Oct 2020 15:52:27

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:54
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, please confirm swab sample collected on 31AUG2020, per Preclarus report samples collected for the subject US3212013 on 31AUG2020 under Unscheduled Visit with accession number " 1F621004502" and Requisition kit id "1F640048858" however same is missing in EDC. Please reconcile the data, if any subject id mismatch or visit mismatch and raise a data clarification form to Preclarus. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:59:38
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, please confirm swab sample collected on 31AUG2020, per Preclarus report samples collected for the subject US3212013 on 31AUG2020 under Unscheduled Visit with accession number " 1F621004502" and Requisition kit id "1F640048858" however same is missing in EDC. Please reconcile the data, if any subject id mismatch or visit mismatch and raise a data clarification form to Preclarus. Else clarify, thank you.' answered with 'entered' (Site from DM).	Reagan Reed (b) (4)	01 Apr 2021 13:53:04
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted however, please confirm swab sample collected on 31AUG2020, per Preclarus report samples collected for the subject US3212013 on 31AUG2020 under Unscheduled Visit with accession number " 1F621004502" and Requisition kit id "1F640048858" however same is missing in EDC. Please reconcile the data, if any subject id mismatch or visit mismatch and raise a data clarification form to Preclarus. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:37:15
User closed query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:37:15

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Visit Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form.' answered with 'subject was seen for V2 on this date as well. data captured there' (Site from DM).	Reagan Reed (b) (4)	24 Mar 2021 13:53:16
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:16:53
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:11:16
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'you have queried a missing data entry on the exact data entry slot for the supposed missing data... this is an unsched. visit data entry conducted on 31AUG2020. The full visit is entered and the samples are in PPD lab portal. ' (Site from DM).	Reagan Reed (b) (4)	12 Feb 2021 18:44:54
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 31AUG2020 under Unscheduled in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 04:06:07

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Visit Date](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	14 Jan 2021 15:54:28

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:54
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:28

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:54
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:28

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:54
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:28

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:44:16

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:02:54
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:28

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '16:13'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User entered '31 Aug 2020 16:13'	System	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '98.4' F	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (Oral)'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '83'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User entered 'bpm'	System	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '17'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User entered 'breaths/min'	System	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '135'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User entered 'mmHg'	System	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '88'	Afifah Ayub (b) (4)	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00
User entered 'mmHg'	System	14 Jan 2021 15:54:59

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 15:44:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:00

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:07
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Jan 2021 15:55:18

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Physical Examination

Generated On: 09 Jun 2021 15:44:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:07
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	14 Jan 2021 15:55:18

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	14 Jan 2021 15:55:35

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '31 Aug 2020'	Afifah Ayub (b) (4)	14 Jan 2021 15:55:35

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:14
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '16:35'	Afifah Ayub (b) (4)	14 Jan 2021 15:55:35

US3212013

Folder: Unscheduled 31 Aug 2020

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:44:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:03:14
User entered '31 Aug 2020 16:35'	System	14 Jan 2021 15:55:35

US3212013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:44:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:38
User entered 'Yes (Y)' reason for change: New Information	Heather Leary (b) (4)	31 Aug 2020 20:37:22
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 14:01:56

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:05:09
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:50:42
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	01 Sep 2020 15:50:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Query 'PV Query: As per the query response abnormal uterine bleeding is related to medical history of uterine fibroids. Since, abnormal uterine bleeding is a symptom of a medical condition (intramural uterine fibroid worsening), therefore please consider updating the event verbatim on the SAE form accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 13:38:40
User opened query 'PV Query: As per the query response abnormal uterine bleeding is related to medical history of uterine fibroids. Since, abnormal uterine bleeding is a symptom of a medical condition (intramural uterine fibroid worsening), therefore please consider updating the event verbatim on the SAE form accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 12:28:56
Query 'PV Query: As per the query response abnormal uterine bleeding is related to medical history of uterine fibroids. Since, abnormal uterine bleeding is a symptom of a medical condition (intramural uterine fibroid worsening), therefore please consider updating the event verbatim on the SAE form accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:55:51
User opened query 'PV Query: As per the query response abnormal uterine bleeding is related to medical history of uterine fibroids. Since, abnormal uterine bleeding is a symptom of a medical condition (intramural uterine fibroid worsening), therefore please consider updating the event verbatim on the SAE form accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 23:33:05
User closed query 'PV Query: Please provide the results of any diagnostic tests (i.e. pelvic ultrasound, endometrial biopsy, etc). ' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:28:41
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 20:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	26 Oct 2020 20:28:39
Data point term sent to Coder	System	26 Oct 2020 20:27:15

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 20:26:54
	(b) (4)	
Coding entries removed.	Afifah Ayub (b) (4)	26 Oct 2020 20:26:54
	(b) (4)	
User entered 'abnormal UTERINE BLEEDING' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:26:54
	(b) (4)	
Query 'PV Query: Please provide the results of any diagnostic tests (i.e. pelvic ultrasound, endometrial biopsy, etc). ' answered with 'Medical Records not available ' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:20:12
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:08:59
User opened query 'PV Query: Please provide the results of any diagnostic tests (i.e. pelvic ultrasound, endometrial biopsy, etc). ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:37:54
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:10:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 21:10:48
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 21:09:30
Coding entries removed.	Heather Leary (b) (4)	31 Aug 2020 21:09:03
	(b) (4)	
User entered 'UTERINE bleeding' reason for change: Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 21:09:03
	(b) (4)	
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:45:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 20:45:41
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 20:44:38
User entered 'Uterine Hemorrhage'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:01
User entered 'Yes (Y)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:22
User entered 'No (N)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:26
User entered '27 Aug 2020'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:31
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 20:44:39
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 20:44:39
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Aug 2020 20:44:06
User entered '00:01'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:44:39
User entered '27 Aug 2020 00:01'	System	31 Aug 2020 20:44:06

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:09:33
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:35
User entered '28 Aug 2020'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:37
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	31 Aug 2020 20:44:39
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 20:44:39
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	31 Aug 2020 20:44:06
User entered '12:01'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 20:44:39
User entered '28 Aug 2020 12:01'	System	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:39
	(b) (4), (b) (6)	
User closed query ' PV Query: As the subject required hospitalization, please consider updating intensity from grade 2 to grade 3. If not updated, please clarify in your response. ' (Site from Safety).		02 Oct 2020 12:30:36
Query ' PV Query: As the subject required hospitalization, please consider updating intensity from grade 2 to grade 3. If not updated, please clarify in your response. ' answered with 'updated' (Site from Safety).	Heather Leary (b) (4)	01 Oct 2020 20:20:52
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Heather Leary (b) (4)	01 Oct 2020 20:20:38
	(b) (4)	
User opened query ' PV Query: As the subject required hospitalization, please consider updating intensity from grade 2 to grade 3. If not updated, please clarify in your response. ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:37:36
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:09:45
User entered '0'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:09:47
User entered '0'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:49
User entered 'I'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:51
User entered '27 Aug 2020'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:09:53
User entered '28 Aug 2020'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:10:00
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:02
User entered empty.	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:10:04
User entered '0'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:10:05
User entered '0'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

US3212013

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4) [REDACTED]	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Oct 2020 15:10:07
User entered '0'	Heather Leary (b) (4) (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:08
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:16:24
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:29:42
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:29:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Sep 2020 14:29:42
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	(b) (4)	31 Aug 2020 20:44:39
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	31 Aug 2020 20:44:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 20:44:39
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	(b) (4)	31 Aug 2020 20:44:06
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:10
User entered 'Not Related (NOT RELATED)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
User closed query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject receive the second dose of study vaccine? If yes, please provide the date.' (Site from Safety).		22 Dec 2020 18:17:10
Query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject receive the second dose of study vaccine? If yes, please provide the date.' answered with 'please see Visit 2 - date of vaccination confirmation ' (Site from Safety).	Reagan Reed (b) (4)	21 Dec 2020 16:00:43
	(b) (4)	
User opened query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject receive the second dose of study vaccine? If yes, please provide the date.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:56:30
User closed query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject received second dose of study vaccine? If yes, please provide date.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:28:45
Query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject received second dose of study vaccine? If yes, please provide date.' answered with 'Yes 07Oct2020' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:50:20
User opened query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject received second dose of study vaccine? If yes, please provide date.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:48:23
User closed query 'Per source, dose was delayed. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:38:14
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:38:10
Query 'Per source, dose was delayed. Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).	Heather Leary (b) (4)	15 Oct 2020 19:19:37
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Oct 2020 19:19:28
	(b) (4)	

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per source, dose was delayed. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:26:52
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 15:26:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:12
Query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:26:11
User opened query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:25:23
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:13
User entered '0'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:15
	(b) (4), (b) (6)	
User closed query 'PV Query: Please add hormonal contraceptive and any additional treatment to CM eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).		02 Oct 2020 12:30:44
Query 'PV Query: Please add hormonal contraceptive and any additional treatment to CM eCRF (including dates of administration, dose, units, frequency, route and indication). ' answered with 'conmeds have been updated' (Site from Safety).	Heather Leary (b) (4)	01 Oct 2020 20:21:43
	(b) (4)	
User opened query 'PV Query: Please add hormonal contraceptive and any additional treatment to CM eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:38:16
User entered 'I'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:10:15
	(b) (4), (b) (6)	14 Oct 2020 15:10:20
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'procedures have been updated' (Site from DM).	Heather Leary (b) (4)	01 Oct 2020 20:22:07
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:39:20
User entered 'I'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:44:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:10:26
User entered empty.	Heather Leary (b) (4)	31 Aug 2020 20:44:06
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
User closed query 'PV Query: Abnormal uterine bleeding occurred before administration of IP? If so, please consider adding it to the medical history, if the origin of bleeding has not been reported.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 16:25:08
User closed query 'PV Query: Please provide the bleeding origin. Was the bleeding from the intramural uterine fibroid? If not, please explain' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 16:24:59
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).	(b) (4), (b) (6)	14 Jan 2021 16:24:21
Query 'PV Query: Abnormal uterine bleeding occurred before administration of IP? If so, please consider adding it to the medical history, if the origin of bleeding has not been reported.' answered with 'Please explain query - as per Section 8.2.3. of PA6 -	(b) (4), (b) (6)	13 Jan 2021 22:28:19
Significant findings that were present prior to the signature of the informed consent will also be included in the Medical History eCRF page.		
Medical History for this subject includes Intramural Uterine Fibroids.		
Abnormal Uterine Bleeding is an SAE based on Inpatient Hospitalization as Section 8.3.3 of PA6. ' (Site from Safety).		
Query 'PV Query: Please provide the bleeding origin. Was the bleeding from the intramural uterine fibroid? If not, please explain' answered with 'Yes, bleeding from intramural uterine fibroid' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 22:16:44
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No relevant laboratory and diagnostic test results received. ' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 22:15:24

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Abnormal uterine bleeding occurred before administration of IP? If so, please consider adding it to the medical history, if the origin of bleeding has not been reported.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:56:54
User opened query 'PV Query: Please provide the bleeding origin. Was the bleeding from the intramural uterine fibroid? If not, please explain' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 23:56:40
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).	(b) (4), (b) (6)	03 Dec 2020 23:56:02
User closed query 'PV Query: The following was provided in a query response, "subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration". Please add "episodes of severe or prolonged uterine bleeding" to medical history in EDC.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:00:23
Query 'PV Query: The following was provided in a query response, "subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration". Please add "episodes of severe or prolonged uterine bleeding" to medical history in EDC.' answered with 'Subject has Fibroids noted in Medical History. ' (Site from Safety).	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 21:52:47
User opened query 'PV Query: The following was provided in a query response, "subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration". Please add "episodes of severe or prolonged uterine bleeding" to medical history in EDC.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 19:15:36
User closed query 'PV Query: Please add the episodes of severe, prolonged uterine bleeding reported in query response to the subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:03:28
Query 'PV Query: Please add the episodes of severe, prolonged uterine bleeding reported in query response to the subject's medical history.' answered with 'Please clarify this query - AE is of "ABNORMAL" Uterine bleeding is added.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 22:09:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add the episodes of severe, prolonged uterine bleeding reported in query response to the subject's medical history.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 20:57:53
User closed query 'PV Query: Did the subject receive the second dose of IP administration?' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:29:00
User closed query 'PV Query: Please clarify if the subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration?' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:28:59
User closed query 'PV query: What was the etiology/cause of the uterine bleeding (i.e. uterine fibroids, hormonal imbalance, etc) ' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:28:57
User closed query 'PV Query: Please provide the subject's hemoglobin and hematocrit pre and post blood transfusion (including units and reference range). ' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:28:56
User closed query 'PV Query: Please confirm if all bleeding had subsided at event resolution and provide update on subject's current status. ' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 14:28:53
Query 'PV Query: Did the subject receive the second dose of IP administration?' answered with 'Yes' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 20:12:04
Query 'PV Query: Please clarify if the subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration?' answered with 'Yes- subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 20:11:21
Query 'PV query: What was the etiology/cause of the uterine bleeding (i.e. uterine fibroids, hormonal imbalance, etc) ' answered with 'Uterine Fibroids' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 20:11:08
Query 'PV Query: Please provide the subject's hemoglobin and hematocrit pre and post blood transfusion (including units and reference range). ' answered with 'Pre Hb - 6.3, Post transfusion Hb - 10' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 20:10:49

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if all bleeding had subsided at event resolution and provide update on subject's current status. ' answered with 'Yes - all bleeding subsided, healing well from hysterectomy. Hb level was 10 ug/dl at last visit. ' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:52:32
User opened query 'PV Query: Did the subject receive the second dose of IP administration?' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:48:05
User closed query 'Per source, IP was not withdrawn but delayed. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:38:39
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:38:34
User closed query 'Per DM CLR: As per SAE narrative, "SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:10:22
User closed query ' Per DM CLR: As per SAE narrative, "PATIENT HAS A HISTORY OF UTERINE FIBROIDS", however, please note that this MH condition is not recorded in MH eCRF page. Please reconcile and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:10:17
Query 'Per source, IP was not withdrawn but delayed. Heather Leary Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).	(b) (4)	15 Oct 2020 19:20:09

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAS A HISTORY OF UTERINE FIBROIDS. ON 27AUG2020 SHE PRESENTED TO MEMORIAL HERMANN HOSPITAL WITH UTERINE HEMORRHAGE. SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD. SHE WAS PRESCRIBED HORMONAL CONTRACEPTION AS WELL. SHE WAS DISCHARGED ON 28AUG2020. RECORDS WILL BE REQUESTED BY SITE. IP IS BEING DELAYED DUE TO PARTICIPANT'S RECEIVING BLOOD TRANSFUSIONS.' reason for change: Data Entry Error	Heather Leary (b) (4)	15 Oct 2020 19:20:01
User opened query 'Per source, IP was not withdrawn but delayed. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:12:12
User opened query 'PV Query: Please clarify if the subject had episodes of severe or prolonged uterine bleeding prior to blinded study medication administration?' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:00:02
User closed query 'PV query: Please add uterine fibroids to the subject's medical history eCRF page with applicable dates. ' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 12:30:53
Query 'Per DM CLR: As per SAE narrative, "SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD", however, please note that there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' answered with 'ConProc were updated' (Site from DM).	Heather Leary (b) (4)	01 Oct 2020 20:23:40
Query 'Per DM CLR: As per SAE narrative, "PATIENT HAS A HISTORY OF UTERINE FIBROIDS", however, please note that this MH condition is not recorded in MH eCRF page. Please reconcile and update as appropriate, otherwise provide clarification. ' answered with 'MH updated' (Site from DM).	Heather Leary (b) (4)	01 Oct 2020 20:23:31
Query 'PV query: Please add uterine fibroids to the subject's medical history eCRF page with applicable dates. ' answered with 'entry added' (Site from Safety).	Heather Leary (b) (4)	01 Oct 2020 20:23:15

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: As per SAE narrative, "SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD", however, please note tthat there is no ConProc recorded in ConProc eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:40:55
User opened query 'Per DM CLR: As per SAE narrative, "PATIENT HAS A HISTORY OF UTERINE FIBROIDS", however, please note that this MH condition is not recorded in MH eCRF page. Please reconcile and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:40:19
User opened query 'PV query: What was the etiology/cause of the uterine bleeding (i.e. uterine fibroids, hormonal imbalance, etc) ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:39:28
User opened query 'PV Query: Please provide the subject's hemoglobin and hematocrit pre and post blood transfusion (including units and reference range). ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:39:10
User opened query 'PV query: Please add uterine fibroids to the subject's medical history eCRF page with applicable dates. ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:38:53
User opened query 'PV Query: Please confirm if all bleeding had subsided at event resolution and provide update on subject's current status. ' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 15:38:35
Query 'Per ETRTR: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:21:12
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:21:10
User opened query 'Per ETRTR: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication), thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:28:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:27:04
User entered 'PATIENT HAS A HISTORY OF UTERINE FIBROIDS. ON 27AUG2020 SHE PRESENTED TO MEMORIAL HERMANN HOSPITAL WITH UTERINE HEMORRHAGE. SHE WAS ADMITTED TO HOSPITAL AND RECEIVED 3 PINTS OF TRANSFUSED BLOOD. SHE WAS PRESCRIBED HORMONAL CONTRACEPTION AS WELL. SHE WAS DISCHARGED ON 28AUG2020. RECORDS WILL BE REQUESTED BY SITE. IP IS BEING WITHDRAWN DUE TO PARTICIPANT'S RECEIVING BLOOD TRANSFUSIONS.' reason for change: Data Entry Error	Heather Leary (b) (4)	31 Aug 2020 20:45:24
User entered 'Patient has a history of uterine fibroids. On 27AUG2020 she presented to Memorial Hermann hospital with uterine hemorrhage. She was admitted to hospital and received 3 pints of transfused blood. She was prescribed hormonal contraception as well. She was discharged on 28AUG2020. Records will be requested by site.'	Heather Leary (b) (4)	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 20:44:06

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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	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Aug 2020 20:44:06

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 16:26:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 16:26:40
Data point term sent to Coder	System	20 Oct 2020 16:25:50
User entered 'Urinary tract infection'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '12 Oct 2020'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Oct 2020 16:25:17
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	20 Oct 2020 16:25:17
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	20 Oct 2020 16:25:06
User entered '12:00'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User entered empty.	System	20 Oct 2020 16:25:17
User entered '12 Oct 2020 12:00'	System	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 14:21:17
User entered 'Yes (Y)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '19 Oct 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	20 Oct 2020 16:25:06
User entered empty.	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User entered empty.	System	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:54:48
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	18 Nov 2020 15:29:52
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4)	18 Nov 2020 15:29:48
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:58:09
User entered 'Not Applicable (NOT APPLICABLE)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'None (NONE)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 14:21:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Reagan Reed (b) (4)	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User entered '0'	System	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41
User entered 'I'	System	20 Oct 2020 16:25:06

US3212013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:44:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:58:41

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:20
User entered 'USA-US115-2020-mRNA-1273-P301000013'	System	25 Nov 2020 21:02:06
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:06
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 21:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:29:42
User entered 'USA-US115-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	27 Oct 2020 14:29:38

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	23 Mar 2021 06:57:16
User closed query 'Per DM CLR - RQ: Site's response noted. However, AE #1 ended on 28AUG2020 and appears to be a different event from this AE. Please review and consider deleting the term "worsening" from this event. ' (Site from DM).	Coder Import (b) (4)	19 Mar 2021 20:10:47
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\\23.0.	(b) (4)	19 Mar 2021 20:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 20:10:47
Data point term sent to Coder	System	19 Mar 2021 20:09:20
Query 'Per DM CLR - RQ: Site's response noted. However, AE #1 ended on 28AUG2020 and appears to be a different event from this AE. Please review and consider deleting the term "worsening" from this event. ' answered with 'Removed "worsening of" ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:08:51
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 20:08:33
User entered 'ABNORMAL UTERINE BLEEDING' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 20:08:33
User opened query 'Per DM CLR - RQ: Site's response noted. However, AE #1 ended on 28AUG2020 and appears to be a different event from this AE. Please review and consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:22:20
User closed query 'Per DM CLR: Please confirm the AE term "WORSENING OF ABNORMAL UTERINE BLEEDING", as there is no associated baseline Med History condition or Sequential Adverse Event noted. Clarify if this condition is an exacerbation of a baseline condition or sequential AE. If so, please add the corresponding condition to the Med History or AE eCRF. Otherwise, consider deleting the term "worsening" from this event.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:55:34

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm the AE term "WORSENING OF ABNORMAL UTERINE BLEEDING", as there is no associated baseline Med History condition or Sequential Adverse Event noted. Clarify if this condition is an exacerbation of a baseline condition or sequential AE. If so, please add the corresponding condition to the Med History or AE eCRF. Otherwise, consider deleting the term "worsening" from this event.' answered with 'please see AE line item #1' (Site from DM).	Reagan Reed (b) (4)	23 Nov 2020 18:48:09
User opened query 'Per DM CLR: Please confirm the AE term "WORSENING OF ABNORMAL UTERINE BLEEDING", as there is no associated baseline Med History condition or Sequential Adverse Event noted. Clarify if this condition is an exacerbation of a baseline condition or sequential AE. If so, please add the corresponding condition to the Med History or AE eCRF. Otherwise, consider deleting the term "worsening" from this event.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:33:30
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Uterine haemorrhage, LLT: Uterine bleeding - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 21:46:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 21:46:31
Data point term sent to Coder	System	26 Oct 2020 20:29:18
User entered 'Worsening of Abnormal Uterine Bleeding'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
User closed query 'Per sponsor review, as event is SAE, please update field to YES.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:18:25
Query 'Per sponsor review, as event is SAE, please update field to YES.' answered with 'updated to yes' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 22:29:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 22:29:15
User opened query 'Per sponsor review, as event is SAE, please update field to YES.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:45:00
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22 Sep 2020'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 20:29:03

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22 Sep 2020'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 20:29:03

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Grade 3/Severe (Grade 3/Severe)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
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).	System	26 Oct 2020 20:49:06
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	26 Oct 2020 20:49:06
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	26 Oct 2020 20:29:03
User entered 'I'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:49:06
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'PV Query: Please confirm hospital discharge date. Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:16:27
Query 'PV Query: Please confirm hospital discharge date. Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'kept in hospital overnight for observation discharged next morning' (Site from Safety).	Reagan Reed (b) (4)	05 Nov 2020 16:19:26
	(b) (4)	
User entered '23 Sep 2020' reason for change: Data Entry Error	Reagan Reed (b) (4)	05 Nov 2020 16:19:02
	(b) (4)	
User opened query 'PV Query: Please confirm hospital discharge date. Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 20:58:35
User entered '22 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:49:06
	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:49:06
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Dose Delayed (DOSE DELAYED)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:51:11
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 14:35:41
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Jagruti Patel (b) (4)	05 Apr 2021 14:35:41
	(b) (4)	
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Mar 2021 18:25:07
User entered '1' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 18:25:07
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Mar 2021 18:24:49
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		24 Nov 2020 15:00:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	23 Nov 2020 21:48:28
User entered '0' reason for change: Data Entry Error	(b) (4)	23 Nov 2020 21:48:24
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 09:33:39
User entered '1'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	06 Apr 2021 14:51:11
	(b) (4), (b) (6)	06 Apr 2021 11:57:10
User closed query 'Per DM CLR: Responses noted, however, please update the response to Yes if Con Proc #2 (ELECTIVE HYSTERECTOMY) was the treatment for this AE. Otherwise, clarify.' (Site from DM).	Jagruti Patel (b) (4)	05 Apr 2021 14:35:55
Query 'Per DM CLR: Responses noted, however, please update the response to Yes if Con Proc #2 (ELECTIVE HYSTERECTOMY) was the treatment for this AE. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jagruti Patel (b) (4)	05 Apr 2021 14:35:41
Signature has been broken.	Jagruti Patel (b) (4)	05 Apr 2021 14:35:41
User entered '1' reason for change: Data Entry Error	Jagruti Patel (b) (4)	03 Apr 2021 05:35:32
User opened query 'Per DM CLR: Responses noted, however, please update the response to Yes if Con Proc #2 (ELECTIVE HYSTERECTOMY) was the treatment for this AE. Otherwise, clarify.' (Site from DM).	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User signature succeeded.	(b) (4), (b) (6)	26 Mar 2021 12:20:52
User closed query 'Per CDM: Narrative indicates 'SUBJECT UNDERWENT HYSTERECTOMY FOR UTERINE BLEEDING/FIBROIDS'. Please verify if this pertains to # 2 'ELECTIVE HYSTERECTOMY' (22-SEP-2020) in the Concomitant Procedure eCRF? If yes, please review and update Other Action Taken as appropriate.' (Site from DM).	Reagan Reed (b) (4)	24 Mar 2021 13:27:23
Query 'Per CDM: Narrative indicates 'SUBJECT UNDERWENT HYSTERECTOMY FOR UTERINE BLEEDING/FIBROIDS'. Please verify if this pertains to # 2 'ELECTIVE HYSTERECTOMY' (22-SEP-2020) in the Concomitant Procedure eCRF? If yes, please review and update Other Action Taken as appropriate.' answered with 'correct' (Site from DM).		

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Narrative indicates 'SUBJECT UNDERWENT HYSTERECTOMY FOR UTERINE BLEEDING/FIBROIDS'. Please verify if this pertains to # 2 'ELECTIVE HYSTERECTOMY' (22-SEP-2020) in the Concomitant Procedure eCRF? If yes, please review and update Other Action Taken as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:55:43
User closed query 'Per DM CLR RQ 2: Previous response noted. However since concomitant procedure was performed due to this AE,so Indication is expected to be recorded as Adverse event to make the data appropriate match.Please review and update the ecRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:50:36
Query 'Per DM CLR RQ 2: Previous response noted. However since concomitant procedure was performed due to this AE,so Indication is expected to be recorded as Adverse event to make the data appropriate match.Please review and update the ecRF as appropriate.' answered with 'updated' (Site from DM).	Jagruti Patel (b) (4)	23 Mar 2021 18:26:29
User entered '0' reason for change: Data Entry Error	Jagruti Patel (b) (4)	23 Mar 2021 18:24:49
User opened query 'Per DM CLR RQ 2: Previous response noted. However since concomitant procedure was performed due to this AE,so Indication is expected to be recorded as Adverse event to make the data appropriate match.Please review and update the ecRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:04:41
Query 'Per DM CLR RQ 2: Previous response is noted. However since this concomitant procedure was performed due to this AE,so Indication is expected to be recorded as Adverse event so that there is appropriate match.Please review and update the data as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:03:37
User opened query 'Per DM CLR RQ 2: Previous response is noted. However since this concomitant procedure was performed due to this AE,so Indication is expected to be recorded as Adverse event so that there is appropriate match.Please review and update the data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:03:16

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EAB) (1725)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, if the procedure was done for this AE, then the ConProc indication should be Adverse Event. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:03:16
Query 'Per DM CLR - RQ: Site's response noted. However, if the procedure was done for this AE, then the ConProc indication should be Adverse Event. Update eCRF as appropriate.' answered with 'Only medical diagnosis / condition are recorded as AEs. Please clarify what's needed from us. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:16:22
User opened query 'Per DM CLR - RQ: Site's response noted. However, if the procedure was done for this AE, then the ConProc indication should be Adverse Event. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 07:23:59
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:25:29
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'Con Procedure of hysterectomy was performed due to the SAE of Worsening of abnormal uterine bleeding - it is linked appropriately.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 22:47:29
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 01:28:55

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Afifah Ayub (b) (4) (b) (4)	26 Oct 2020 20:29:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Form: Adverse Events (4)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	22 Mar 2021 20:42:52
User closed query 'PV Query: Abnormal uterine bleeding occurred before administration of IP? If so, please consider adding it to the medical history, if the origin of bleeding has not been reported.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 20:42:46
User closed query 'PV Query: Please provide the bleeding origin. Was the bleeding from the intramural uterine fibroid? If not, please explain' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 20:42:42
User closed query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject receive the second dose of study vaccine? If yes, please provide the date.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 20:42:38
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).	(b) (4), (b) (6)	19 Mar 2021 20:22:57
Query 'PV Query: Abnormal uterine bleeding occurred before administration of IP? If so, please consider adding it to the medical history, if the origin of bleeding has not been reported.' answered with 'Subject received first dose on 03Aug2020 and date of SAE #1 was 27AUG2020 and SAE #2 WAS ON 22SEP2020. CRF entries are correct as is.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:19:30
Query 'PV Query: Please provide the bleeding origin. Was the bleeding from the intramural uterine fibroid? If not, please explain' answered with 'Yes- bleeding was from intramural uterine fibroid' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:19:01
Query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject receive the second dose of study vaccine? If yes, please provide the date.' answered with 'Yes, on 07Oct2020.' (Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[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 'laboratory and diagnostic test results not available ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:17:57
User opened query 'PV Query: Abnormal uterine bleeding occurred before administration of IP? If so, please consider adding it to the medical history, if the origin of bleeding has not been reported.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 18:12:01
User opened query 'PV Query: Please provide the bleeding origin. Was the bleeding from the intramural uterine fibroid? If not, please explain' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 18:10:38
User opened query 'PV Query: It was reported study vaccine was delayed in response to the events. Did the subject receive the second dose of study vaccine? If yes, please provide the date.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 18:10:07
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).	(b) (4), (b) (6)	22 Jan 2021 18:09:41
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Oct 2020 20:29:20
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 20:29:20
User entered 'Subject underwent hysterectomy for uterine bleeding/fibroids.' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:29:20
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Oct 2020 20:29:03
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 20:29:03

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Folder: Adverse Events

Form: Adverse Events (4)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 20:29:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:44:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 22:29:15
User entered '0'	System	26 Oct 2020 20:29:03

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 20:49:06

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue infections and inflammations NEC, PT: Plantar fasciitis, LLT: Plantar fasciitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 23:51:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 23:51:53
Data point term sent to Coder	System	05 Nov 2020 14:22:47
Coding entries removed.	Afifah Ayub (b) (4)	05 Nov 2020 14:22:18
	(b) (4)	
User entered 'right FOOT PAIN (plantar fasciitis)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 14:22:18
	(b) (4)	
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: Pain in extremity, LLT: Foot pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:41
Data point term sent to Coder	System	28 Oct 2020 20:36:47
User entered 'foot pain'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22 Oct 2020'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:35:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:35:55

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Afifah Ayub (b) (4)	05 Nov 2020 14:22:18
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 14:22:18
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	05 Nov 2020 14:22:18
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'None (NONE)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

None

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:35:55
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 20:35:55

US3212013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:44:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 20:35:55

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Vulvovaginal candidiasis, LLT: Vaginal candidiasis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:24:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 14:24:20
Data point term sent to Coder	System	05 Nov 2020 14:23:48
User entered 'Vaginal Candidiasis'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '20 Oct 2020'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:23:46

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Nov 2020 16:13:29
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	05 Nov 2020 16:13:29
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Nov 2020 14:23:46
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 14:23:46

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Related (NOT RELATED)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Not Applicable (NOT APPLICABLE)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:13:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:13:39
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Reagan Reed (b) (4)	05 Nov 2020 16:13:39
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:13:29
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	05 Nov 2020 16:13:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	05 Nov 2020 14:23:46
	(b) (4)	

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:23:46

US3212013

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:44:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 14:23:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:44:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:33:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:10:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:16:10
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:16:10
	(b) (4)	
Data point term sent to Coder	System	03 Aug 2020 21:12:21
User entered 'Oxybutynin'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:32
User closed query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:00:30
Query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	21 Sep 2020 14:59:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	21 Sep 2020 14:58:53
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:28:31
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:11:49
	(b) (4), (b) (6)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:35
User entered 'Urinary Incontinence'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:37
User entered '5'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:39
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:41
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:44
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:42:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:44:29
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:44:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:35:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 21:21:20
User entered 'UN UNK 2019'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:44:40
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:44:45
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:44:49
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 21:11:49

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:46:45
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 MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 12:21:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 12:21:45
	(b) (4)	
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 SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 21:25:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 21:25:49
	(b) (4)	
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 SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 13:11:05
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Esmoprazole (Nexium)'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	04 Aug 2020 13:11:05 03 Aug 2020 21:14:24 03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:46:47
User closed query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:00:34
Query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	21 Sep 2020 14:59:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	21 Sep 2020 14:59:20
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:25:48
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:13:51
	(b) (4), (b) (6)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:46:49
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:46:52
User entered '20'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:46:54
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:46:56
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:02
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:07
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:35:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 21:21:20
User entered 'UN UNK 2019'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:13
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:17
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:26
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 21:13:51

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:47:41
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, PRODUCTSYNONYM: FERROUS SULPHATE [FERROUS SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 23:31:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 23:31:06
Data point term sent to Coder	System	03 Aug 2020 21:15:24
User entered 'Ferrous Sulphate'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per source, answer is No. Please verify and update accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:39:45
	(b) (4), (b) (6)	23 Oct 2020 14:39:43
Query 'Per source, answer is No. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	14 Oct 2020 17:02:18
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Oct 2020 17:02:13
User opened query 'Per source, answer is No. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:51:01
User closed query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:00:37
Query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	21 Sep 2020 14:59:51
User opened query 'Per DM CLR: Prophylaxis=YES. However, there is corresponding MH condition that matches this con med and is within the time frame. Please review and verify if this can be changed to NO. if yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:28:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:52:03
User entered 'Iron Deficiency'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:52:08
User entered '65'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:52:11
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:52:15
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:55:29
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:35:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 21:21:20
User entered 'UN UNK 2018'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:14
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Reagan Reed (b) (4)	27 Oct 2020 17:42:54
User entered 'No (N)' reason for change: New Information	Reagan Reed (b) (4)	27 Oct 2020 17:42:54
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Reagan Reed (b) (4)	27 Oct 2020 17:42:54
User entered 'UN Aug 2020' reason for change:	Reagan Reed (b) (4)	27 Oct 2020 17:42:54
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:17
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:56:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User entered '1'	System	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User entered '1'	System	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:25
User entered '804 (804)'	System	03 Aug 2020 21:15:13

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:58:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 22:40:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 22:40:12
	(b) (4)	
Data point term sent to Coder	System	03 Aug 2020 21:17:26
User entered 'Cetirizine (Zyrtec)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	
User closed query 'Per source, the answer in no. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:41:01
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:40:59
Query 'Per source, the answer in no. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	14 Oct 2020 17:03:41
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Oct 2020 17:03:36
User opened query 'Per source, the answer in no. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:00:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:11
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:15
User entered '10'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:16
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:18
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:20
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:23
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:29
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:35:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 21:21:20
User entered 'UN UNK 2010'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:33
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:37
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:39
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:16:38

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:52
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 08:17:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 08:17:50
Data point term sent to Coder	System	14 Sep 2020 16:15:37
User entered 'Provera'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:55
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:00:57
User entered 'Uterine bleeding'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
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).	(b) (4), (b) (6)	03 Nov 2020 14:54:00
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Anna Pena (b) (4)	19 Oct 2020 16:19:11
DataPoint Un-verified.	Anna Pena (b) (4)	19 Oct 2020 16:19:02
User entered '10' reason for change: Data Entry Error	Anna Pena (b) (4)	19 Oct 2020 16:19:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:03:44
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)	14 Oct 2020 09:40:28
User entered '1'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:03:46
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:03:51
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:03:53
User entered 'twice daily (BID)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:03:57
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:03:59
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:10
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:12
User entered '28 Aug 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:15
User entered '0'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:17
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:20
User entered '29 Aug 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:23
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User entered '2'	System	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User entered '1'	System	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:48:38
User entered '804 (804)'	System	14 Sep 2020 16:15:18

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: SPRINTEC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Apr 2021 13:38:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Apr 2021 13:38:44
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORGESTIMATE, PRODUCTSYNONYM: SPRINTEC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:41:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 15:41:38
Data point term sent to Coder	System	14 Sep 2020 16:17:44
User entered 'Sprintec (norgestimate/ethinyl estradiol)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:37
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:46
User entered 'Uterine bleeding'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:52
User entered '0.25/0.035'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:54
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:56
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:11:57
User entered 'other (OTHER)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:00
User entered 'Take 1 every 6 hours x 4 days, then take 1 every 8 hrs x 3 days, then take 1 every 12 hrs x 2 days, then take 1 daily'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:02
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:04
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:08
User entered '29 Aug 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:14
User entered '0'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:50:30
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:12
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	05 Oct 2020 16:13:42
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	05 Oct 2020 16:13:37
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:43:22
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:16
User entered '04 Sep 2020' reason for change: Per Query Resolution	Afifah Ayub (b) (4)	05 Oct 2020 16:13:37
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:12:18
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User entered empty.	System	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User entered empty.	System	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:45:49
User entered empty.	System	14 Sep 2020 16:17:03

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
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 IRON DEFICIENCY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:59:07
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #3. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:57:06
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 IRON DEFICIENCY should be recorded, and update con med indication or provide clarification. ' answered with 'updated per source' (Site from DM).	Reagan Reed (b) (4) (b) (4)	27 Oct 2020 17:43:33
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #3. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'updated per source' (Site from DM).	Reagan Reed (b) (4) (b) (4)	27 Oct 2020 17:43:17
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:15:54
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #3. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:40:14
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 IRON DEFICIENCY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:40:08

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
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, PRODUCTSYNONYM: FERROUS SULPHATE [FERROUS SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 10:11:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 10:11:45
Data point term sent to Coder	System	14 Sep 2020 16:22:51
User entered 'Ferrous Sulphate'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:15:56
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:15:58
User entered 'Fe Deficiency anemia'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:00
User entered '325'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:02
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:10
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:12
User entered 'three times daily (TID)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:13
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:15
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:17
User entered empty.	Laura Ngansop Djampou	14 Sep 2020 16:22:05
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:20
User entered '27 Aug 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:22
User entered '0'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:23
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:25
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:26
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 16:22:05

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:00:38
Data point term sent to Coder	System	29 Sep 2020 21:52:42
User entered 'Motrin'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:16:38
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:01
User entered 'postoperative pain'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:04
User entered '800'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:06
User entered 'mg (mg)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:09
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:11
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:13
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:15
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:17
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:19
User entered '23 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:22
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:00:39
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:00:39
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:24
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:00:39
User entered '07 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:00:39
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:26
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:29:29
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User entered empty.	System	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User entered empty.	System	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:51:52
User entered empty.	System	29 Sep 2020 21:52:01

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 23:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 23:05:41
Data point term sent to Coder	System	29 Sep 2020 21:53:44
User entered 'Colace'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:07
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:10
User entered 'prevention of constipation with postoperative opioid use; Hysterectomy'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:12
User entered '100'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:15
User entered 'mg (mg)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:17
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:19
User entered 'twice daily (BID)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:21
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:23
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:26
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:28
User entered '23 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:30
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:17:50
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:17:50
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:33
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:17:50
User entered '07 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:17:50
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:37
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:39
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User entered '2'	System	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User entered '1'	System	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:30
User entered '804 (804)'	System	29 Sep 2020 21:52:44

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:51
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.	Coder Import (b) (4)	29 Sep 2020 21:54:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 21:54:39
Data point term sent to Coder	System	29 Sep 2020 21:53:45
User entered 'Acetaminophen'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:53
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:30:58
User entered 'postoperative pain'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:01
User entered '325'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:10
User entered 'mg (mg)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:12
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:15
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:18
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:20
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:22
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:23
User entered '23 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:25
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:18:15
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:18:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:28
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:18:15
User entered '07 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:18:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:29
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:32
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User entered empty.	System	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User entered empty.	System	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:49:50
User entered empty.	System	29 Sep 2020 21:53:14

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:52
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: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:51:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:51:55
Data point term sent to Coder	System	29 Sep 2020 21:54:46
User entered 'Norco (hydrocodone/acetaminophen)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:54
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:31:56
User entered 'postoperative pain'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:01
User entered '5/325'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:03
User entered 'mg (mg)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:06
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:08
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:09
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:11
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:12
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:15
User entered '22 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:16
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:18:47
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:18:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:19
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 21:18:47
User entered '07 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:18:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:21
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:23
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User entered empty.	System	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User entered empty.	System	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:05
User entered empty.	System	29 Sep 2020 21:53:46

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS AND ESTROGENS IN COMBINATION, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: LEVONORGESTREL AND ETHINYL ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 22:13:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 22:13:58
Data point term sent to Coder	System	13 Jan 2021 17:13:02
Coding entries removed.	Heather Leary (b) (4)	13 Jan 2021 17:12:21
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:33
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 08:15:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 08:15:39
Data point term sent to Coder	System	29 Sep 2020 21:54:48
User entered 'Levonorgestrel/ethinyl estradiol'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:36
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame (05SEP2020-21SEP2020). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 08:17:28
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame (05SEP2020-21SEP2020). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4)	13 Jan 2021 17:12:26
DataPoint Un-verified.	Heather Leary (b) (4)	13 Jan 2021 17:12:21
User entered 'ABNORMAL UTERINE BLEEDING' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Jan 2021 17:12:21
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame (05SEP2020-21SEP2020). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 09:42:37
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:32:41
User entered 'Uterine bleeding'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	26 Oct 2020 20:48:16
User entered '0.1/0.02' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 20:48:16
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:36:45
User entered 'UNK'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:36:47
User entered 'mg (mg)'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:36:49
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:36:51
User entered 'once daily (QD)'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:36:53
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:36:54
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:00
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:02
User entered '05 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:03
User entered '0'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:09
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:54:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 21:54:35
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	29 Sep 2020 21:54:35
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:54:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:11
User entered '21 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:14
User entered 'No (N)'	Afifah Ayub (b) (4)	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User entered '1'	System	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User entered '1'	System	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:46:00
User entered '804 (804)'	System	29 Sep 2020 21:54:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:24:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:24:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:43:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:43:38
Data point term sent to Coder	System	16 Oct 2020 20:47:45
User entered 'Amoxicillin Clavulanate'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'urinary tract infection'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '500/125'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mg (mg)'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'twice daily (BID)'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '12 Oct 2020'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:19:52
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '19 Oct 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	26 Oct 2020 21:19:52
User entered empty.	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User entered '2'	System	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User entered '1'	System	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:21
User entered '804 (804)'	System	16 Oct 2020 20:47:30

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 21:17:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 21:17:39
Data point term sent to Coder	System	26 Oct 2020 21:16:54
User entered 'fexofenadine'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'seasonal allergies'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '180'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mg (mg)'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'as needed (PRN)'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'UN UNK 2010'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Oct 2020 21:16:53
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 21:16:53

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 21:16:53

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 21:16:53

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:05:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:05:20
Data point term sent to Coder	System	28 Oct 2020 20:34:45
User entered 'Prednisone'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'foot pain'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '4'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mg (mg)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'other (OTHER)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Tapered dose: 6 today, 5 tomorrow, 4 on 30Oct, 3 on 31Oct, 2 on 1Nov, 1 on 2Nov'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '28 Oct 2020'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:12
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:34:12

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:34:12

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:34:12

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (7 days aftr dose 2).' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 17:29:59
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (7 days aftr dose 2).' answered with 'deviation already noted' (Site from DM).	Reagan Reed (b) (4) (b) (4)	12 Nov 2020 19:19:22
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (7 days aftr dose 2).' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:18:59
User closed query 'Per MM, please confirm if the subject did not meet EC#12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). If met, please report as possible protocol deviation.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:18:24
Query 'Per MM, please confirm if the subject did not meet EC#12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). If met, please report as possible protocol deviation.' answered with 'protocol deviation noted in progress note captured on 04NOV2020' (Site from DM).	Reagan Reed (b) (4) (b) (4)	12 Nov 2020 18:42:29

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per MM, please confirm if the subject did not meet EC#12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening). If met, please report as possible protocol deviation.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:24:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:06:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	29 Oct 2020 20:06:37
Data point term sent to Coder	System	28 Oct 2020 20:35:46
User entered 'Influenza vaccination'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48
	(b) (4)	

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Nov 2020 18:05:37
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'immunization'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0.5'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mL (mL)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'once (ONCE)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Intramuscular (INTRAMUSCULAR)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14 Oct 2020'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14 Oct 2020'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Afifah Ayub (b) (4)	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User entered empty.	System	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User entered empty.	System	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:34
User entered empty.	System	28 Oct 2020 20:34:48

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE, PRODUCTSYNONYM: DIFLUCAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:56:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:56:30
Data point term sent to Coder	System	04 Nov 2020 21:37:22
User entered 'Fluconazole (Diflucan)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'vaginal candidiasis'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '150'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'mg (mg)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'once (ONCE)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Oral (ORAL)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '20 Oct 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '20 Oct 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User entered empty.	System	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User entered empty.	System	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 10:50:43
User entered empty.	System	04 Nov 2020 21:37:09

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ATC: ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 05:03:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 05:03:37
Data point term sent to Coder	System	04 Nov 2020 21:38:23
User entered 'Nystatin'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'vaginal candidiasis'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '1'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Other (OTHER)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	05 Nov 2020 14:29:28
User entered 'application' reason for change: Data Entry Error	Reagan Reed (b) (4)	05 Nov 2020 14:29:28
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	04 Nov 2020 21:38:00
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'as needed (PRN)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Topical (TOPICAL)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '28 Oct 2020'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '0'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty.	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'No (N)'	Laura Ngansop Djampou (b) (4)	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:44:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:38:00

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:44:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:27:51
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	29 Sep 2020 21:36:33
User entered 'No (N)'	Afifah Ayub (b) (4)	26 Aug 2020 18:16:40

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:53
User entered '27 Aug 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:37:10
	(b) (4)	

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:56
User entered 'Blood Transfusion'	Afifah Ayub (b) (4)	29 Sep 2020 21:37:10
	(b) (4)	

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
	(b) (4), (b) (6)	18 Nov 2020 14:03:55
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' (Site from DM).		
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	02 Nov 2020 14:22:49
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	02 Nov 2020 14:22:42
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify..' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 04:32:57
User closed query 'Per CDM: Please review the indication and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 07:08:00
Query 'Per CDM: Please review the indication and update accordingly.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4)	15 Oct 2020 17:35:39
DataPoint Un-verified.	Afifah Ayub (b) (4)	15 Oct 2020 17:35:03
User entered 'Other (OTHER)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	15 Oct 2020 17:35:03
User opened query 'Per CDM: Please review the indication and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:34:09
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:57
User entered 'Adverse Event (AE)'	Afifah Ayub (b) (4)	29 Sep 2020 21:37:10

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:44:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	02 Nov 2020 14:22:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	15 Oct 2020 17:35:03
User entered 'uterine bleeding' reason for change: Data Entry Error	Afifah Ayub (b) (4)	15 Oct 2020 17:35:03
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:37:59
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:37:10
	(b) (4)	

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:10:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:38:09
User entered '22 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 21:37:29

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:10:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:38:11
User entered 'Elective Hysterectomy'	Afifah Ayub (b) (4)	29 Sep 2020 21:37:29

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:10:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User closed query 'Per CDM: Please verify if this pertains to # 4 'ABNORMAL UTERINE BLEEDING' (22-SEP-2020) in the Adverse Event eCRF? If yes, please review and update 'indication' as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 15:06:45
Query 'Per CDM: Please verify if this pertains to # 4 'ABNORMAL UTERINE BLEEDING' (22-SEP-2020) in the Adverse Event eCRF? If yes, please review and update 'indication' as appropriate.' answered with 'listed as related to med hx. please see fibroid entry' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Mar 2021 13:24:58
User opened query 'Per CDM: Please verify if this pertains to # 4 'ABNORMAL UTERINE BLEEDING' (22-SEP-2020) in the Adverse Event eCRF? If yes, please review and update 'indication' as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:57:26
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the MedHistory eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. MedHistory) as appropriate, otherwise clarify..' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:31:58
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the MedHistory eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. MedHistory) as appropriate, otherwise clarify..' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	02 Nov 2020 14:23:16
DataPoint Un-verified.	Afifah Ayub (b) (4) (b) (4)	02 Nov 2020 14:23:07
User entered 'Medical History (MH)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	02 Nov 2020 14:23:07

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:16

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the MedHistory eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. MedHistory) as appropriate, otherwise clarify..' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 04:33:05
User closed query 'Pleas update indication to Uterine Fibroids. ' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:42:44
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:42:36
Query 'Pleas update indication to Uterine Fibroids. ' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	14 Oct 2020 17:23:52
User entered 'Other (OTHER)' reason for change:	Afifah Ayub (b) (4)	14 Oct 2020 17:23:46
Data Entry Error	(b) (4)	
User opened query 'Pleas update indication to Uterine Fibroids. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:38:32
User entered 'Medical History (MH)'	Afifah Ayub (b) (4)	29 Sep 2020 21:37:29
	(b) (4)	

US3212013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:44:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:10:37
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Un-verified.	Afifah Ayub (b) (4)	02 Nov 2020 14:23:07
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	02 Nov 2020 14:23:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:42:39
DataPoint Un-verified.	Afifah Ayub (b) (4)	14 Oct 2020 17:23:46
User entered 'Uterine Fibroids' reason for change:	Afifah Ayub (b) (4)	14 Oct 2020 17:23:46
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:38:34
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:37:29

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:46
User entered '01/Sep/2020 11:51'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '30/Sep/2020 15:29'	System	30 Sep 2020 15:29:40

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:34:31
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 15:29:40

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered '02/Oct/2020 08:31'	System	02 Oct 2020 12:31:47

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:34:31
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 12:31:47

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '15/Oct/2020 20:34'	System	16 Oct 2020 00:34:39

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:30:07
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 00:34:39

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '27/Oct/2020 10:30'	System	27 Oct 2020 14:30:17

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:16:45
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 14:30:17

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '06/Nov/2020 11:16'	System	06 Nov 2020 16:16:58

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:00:32
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 16:16:58

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '24/Nov/2020 08:00'	System	24 Nov 2020 13:00:43

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:02:38
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 13:00:43

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25/Nov/2020 14:02'	System	25 Nov 2020 14:02:59

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:04:07
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 14:02:59

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25/Nov/2020 16:04'	System	25 Nov 2020 21:04:32

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 18:18:04
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 21:04:32

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered	System	01 Sep 2020 15:50:28
'USA-US115-2020-MRNA-1273-P301000003'		

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:57:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:07
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'Yes (Y)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:11
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:15
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered 'No (N)'	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:20
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
DataPoint Un-verified.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:58:22
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:02:49
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:42:51
Amendment Manager: User entered empty.	System	14 Sep 2020 21:42:51
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 15:51:07
User entered (b) (6)	System	01 Sep 2020 15:50:28

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:00:09
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 15:29:25
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:27:59
User entered 'US' (non-conformant).	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	22 Dec 2020 18:18:46
User entered '9'	System	25 Nov 2020 21:04:32
User entered '8'	System	25 Nov 2020 14:02:59
User entered '7'	System	24 Nov 2020 13:00:43
User entered '6'	System	06 Nov 2020 16:16:58
User entered '5'	System	27 Oct 2020 14:30:17
User entered '4'	System	16 Oct 2020 00:34:39
User entered '3'	System	02 Oct 2020 12:31:47
User entered '2'	System	30 Sep 2020 15:29:40
User entered '1'	System	01 Sep 2020 15:51:15

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22/Dec/2020 18:18'	System	22 Dec 2020 18:18:46

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 18:18:46

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'USA-US115-2020-MRNA-1273-P301000005'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Yes (Y)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Yes (Y)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Vicki'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Miller'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'US'	System	30 Sep 2020 15:29:40

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'USA-US115-2020-MRNA-1273-P301000005'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Yes (Y)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Yes (Y)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'No (N)'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Vicki'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'Miller'	System	30 Sep 2020 14:21:36

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:04:02
User entered 'US'	System	30 Sep 2020 15:29:40

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'USA-US115-2020-MRNA-1273-P301000013'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Vicki'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Miller'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'US'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	06 Apr 2021 17:03:18
User entered '4'	System	24 Mar 2021 19:32:45
User entered '3'	System	22 Mar 2021 18:27:58
User entered '2'	System	14 Jan 2021 15:52:14
User entered '1'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'USA-US115-2020-MRNA-1273-P301000013'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Vicki'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Miller'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'US'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	06 Apr 2021 17:03:18
User entered '4'	System	24 Mar 2021 19:32:45
User entered '3'	System	22 Mar 2021 18:27:58
User entered '2'	System	14 Jan 2021 15:52:14
User entered '1'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '25/Nov/2020 16:03'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'USA-US115-2020-MRNA-1273-P301000013'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Vicki'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Miller'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'US'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	06 Apr 2021 17:03:18
User entered '4'	System	24 Mar 2021 19:32:45
User entered '3'	System	22 Mar 2021 18:27:58
User entered '2'	System	14 Jan 2021 15:52:14
User entered '1'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '14/Jan/2021 10:52'	System	14 Jan 2021 15:52:14

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 15:52:14

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'USA-US115-2020-MRNA-1273-P301000013'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Vicki'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Miller'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'US'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	06 Apr 2021 17:03:18
User entered '4'	System	24 Mar 2021 19:32:45
User entered '3'	System	22 Mar 2021 18:27:58
User entered '2'	System	14 Jan 2021 15:52:14
User entered '1'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '22/Mar/2021 14:27'	System	22 Mar 2021 18:27:58

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 18:27:58

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'USA-US115-2020-MRNA-1273-P301000013'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Vicki'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Miller'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'US'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	06 Apr 2021 17:03:18
User entered '4'	System	24 Mar 2021 19:32:45
User entered '3'	System	22 Mar 2021 18:27:58
User entered '2'	System	14 Jan 2021 15:52:14
User entered '1'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered '24/Mar/2021 12:32'	System	24 Mar 2021 19:32:45

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:03:07
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 19:32:45

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'USA-US115-2020-MRNA-1273-P301000013'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Yes (Y)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'No (N)'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Vicki'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Vicki'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
	(b) (4)	
Un-reviewed for Safety.	System	06 Apr 2021 17:03:18
Signature has been broken.	System	06 Apr 2021 17:03:18
User entered 'Miller'	System	06 Apr 2021 17:03:18
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:28:18
Un-reviewed for Safety.	System	22 Mar 2021 18:27:58
User entered empty.	System	22 Mar 2021 18:27:58
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 21:02:55
User entered 'Miller'	System	25 Nov 2020 21:02:06

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Vicki Miller (b) (4)	26 Mar 2021 17:23:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 15:52:18
User entered 'US'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:44:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	06 Apr 2021 17:03:18
User entered '4'	System	24 Mar 2021 19:32:45
User entered '3'	System	22 Mar 2021 18:27:58
User entered '2'	System	14 Jan 2021 15:52:14
User entered '1'	System	25 Nov 2020 21:03:08

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:44:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
User entered '06/Apr/2021 12:03'	(b) (4) System	06 Apr 2021 17:03:18

US3212013

Folder: SAE USA-US115-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:44:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Insiya Valika (b) (4)	06 Apr 2021 23:32:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:03:18