

US3092022 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:04:00

All time stamps listed in this document are displayed in GMT

US3092022

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:04:00

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[Participant ID](#)

US3092022

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

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US3092022

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3092022

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3092022

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Date of Informed Consent (*dd MMM yyyy*) 5 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

US3092022

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3092022

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 07 Mar 2021 18:17:21

Generated On: 09 Jun 2021 15:04:00

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	HYPERLIPIDEMIA
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)	



US3092022

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	ANXIETY
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)	

US3092022

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	LEFT SHOULDER SURGERY (DUE TO INJURY)
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)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	SENSORY NEUROPATHY BILATERAL FEET
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3092022

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	PROSTATECTOMY
Start date (dd MMM yyyy)	UN UNK 2010
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	CHRONIC NECK PAIN DUE TO INJURY
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)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	BACK PAIN DUE TO INJURY
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)	



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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	HISTORY OF DIZZINESS SECONDARY TO NECK INJURY SUSTAINED IN MILITARY
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)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	LEFT SHOULDER INJURY
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)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2010
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	BRADYCARDIA
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)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Condition	NECK INJURY (SUSTAINED IN MILITARY)
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)	_____



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	12:10 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:10
Height ( <i>xxx.x</i> )	181.5 cm
Weight ( <i>xxx.x</i> )	115.0 kg
BMI ( <i>xxx.x</i> )	34.90958 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

US3092022

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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**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 ☒

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**Specify**

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**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) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101068

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 ☒

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Height	ND - Not Done
Weight	ND - Not Done

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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)	05 AUG 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 12:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 14:31
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 13:40 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 13:40

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) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 AUG 2020
Collection time (00:00-23:59)	13:34 (24 HR)
Collection date and time (derived)	5 AUG 2020 13:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	5 AUG 2020 13:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**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

97.5 °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 14:33

PC Open Date & Time

05 AUG 2020 14:00

PC Close Date & Time

05 AUG 2020 16:30

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 AUG 2020 17:25

PC Close Date & Time

06 AUG 2020 11:59



US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 13:36

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 08:38

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 22:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.5 °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

10 AUG 2020 22:41

---

PC Open Date & Time

10 AUG 2020 12:00

---

PC Close Date & Time

11 AUG 2020 11:59

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US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 09:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 14:34

PC Open Date & Time

05 AUG 2020 14:00

PC Close Date & Time

05 AUG 2020 16:30

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

05 AUG 2020 17:25

PC Close Date & Time

06 AUG 2020 11:59



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**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)

3

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

06 AUG 2020 13:37

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**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

08 AUG 2020 08:40

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**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

09 AUG 2020 22:08

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**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

10 AUG 2020 22:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**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

12 AUG 2020 09:09

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 14:35
PC Open Date & Time	05 AUG 2020 14:00
PC Close Date & Time	05 AUG 2020 16:30



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 AUG 2020 17:25

PC Close Date & Time

06 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**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 ☒

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:38
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 08:43
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Yes ☐

PC Time stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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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US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:42
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**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 ☒

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3092022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

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)	2 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	41 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:59
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3092022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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



US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 12:25 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 12:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3092022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 SEP 2020
Collection time (00:00-23:59)	12:21 (24 HR)
Collection date and time (derived)	02 SEP 2020 12:21

US3092022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:18	02 SEP 2020 12:18
Nasopharyngeal Swab 2	No		

US3092022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:59

PC Open Date & Time

02 SEP 2020 12:45

PC Close Date & Time

02 SEP 2020 15:15

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**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 98.0 °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	03 SEP 2020 10:12
PC Open Date & Time	02 SEP 2020 16:10
PC Close Date & Time	03 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 10:29

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 12:59

PC Open Date & Time

02 SEP 2020 12:45

PC Close Date & Time

02 SEP 2020 15:15

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

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

6

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

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

Yes ☒

No ☐

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

5

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

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 SEP 2020 10:12

PC Open Date & Time

02 SEP 2020 16:10

PC Close Date & Time

03 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**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

04 SEP 2020 10:29

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**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

06 SEP 2020 12:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 12:59
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PC Open Date & Time	02 SEP 2020 12:45
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PC Close Date & Time	02 SEP 2020 15:15
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US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 10:13
PC Open Date & Time	02 SEP 2020 16:10
PC Close Date & Time	03 SEP 2020 11:59



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**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 ☒

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 10:29
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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 ☐

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**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 ☐

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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)

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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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US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Yes ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**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)

114 of 2464

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3092022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	10:40 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 10:40
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> )	55 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3092022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	11:07 (24 HR)
Collection date and time (derived)	7 OCT 2020 11:07

US3092022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:35

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 15:12:05
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Patient Cloud Close Date & Time

13 NOV 2020 23:59



US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

16 NOV 2020 14:07:58

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

01 DEC 2020 10:39:42

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 12:52:00

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

15 DEC 2020 13:12:15

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

---

22 DEC 2020 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

29 DEC 2020 15:29:50

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

05 JAN 2021 12:21:38

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

11 JAN 2021 11:22:02

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 11:29:23
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 12:30:04

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 12:59:30
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

<b>TIMEPOINT</b>	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 13:22:33
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

26 FEB 2021 09:43:08

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

13 MAR 2021 20:05:02

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 10:58:29
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 12:57:36

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

02 APR 2021 23:05:27

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 00:58:32

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

19 APR 2021 01:02:38

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:31:39

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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

30 APR 2021 19:13:42

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 327

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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°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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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°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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 649

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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°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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2022 23:59



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2022 23:59

US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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"/>

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2022 23:59
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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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°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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59



US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

**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 ☐

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

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US3092022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3092022

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:04:00

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		02 MAR 2021 10:43:08

US3092022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3092022

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 JAN 2021

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

Comments 1ST ATTEMPT ON 12/28/20  
2ND ATTEMPT ON 12/30/20  
If Contact Not Made, please provide Comments 3RD ATTEMPT ON 01/04/21

US3092022

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:34

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 02:36:18

Generated On: 09 Jun 2021 15:04:00

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

Visit date (dd MMM yyyy)	01 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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US3092022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 02:36:18

Generated On: 09 Jun 2021 15:04:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:12 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 14:12
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> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 02:36:18

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 APR 2021

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



US3092022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 00:55:17

Generated On: 09 Jun 2021 15:04:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 APR 2021

Collection time (00:00-23:59)

14:24 (24 HR)

Collection date and time (derived)

01 APR 2021 14:24

US3092022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 02:36:18

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092022

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:38:07

Generated On: 09 Jun 2021 15:04:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092022

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:38:07

Generated On: 09 Jun 2021 15:04:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3092022**

**Folder: Safety Call Day 299 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

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*

**US3092022**

**Folder: Safety Call Day 299 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3092022**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:04:00**

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

**US3092022**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 15:04:00**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3092022

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:04:00

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

Visit date (dd MMM yyyy)	20 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3092022

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 02:36:18

Generated On: 09 Jun 2021 15:04:00

Date of updated informed consent (dd MMM yyyy) 20 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 20 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3092022

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:04:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00-23:59)	12:20 (24 HR)
Collection date and time (derived)	20 JAN 2021 12:20

US3092022

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:04:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	12:18
Collection Date and Time (derived)	20 JAN 2021 12:18

US3092022

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:04:00

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3092022

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

AEID	USA-US086-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING DIZZINESS
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)	3 OCT 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)	6 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	06 OCT 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) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

---

SUBJECT WAS HOSPITALIZED  
FOR DIZZINESS CAUSING HIM  
TO FALL. SUBJECT WAS  
INFORMED THAT IT WAS DUE  
TO A NECK INJURY THAT HE  
SUSTAINED WHILE IN THE  
MILITARY. SUBJECT WAS  
HOSPITALIZED FOR 2 DAYS.

---

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

---

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

AEID	
Adverse event	LETHARGY
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)	3 OCT 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)	6 OCT 2020
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 (2)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

AEID

Adverse event

RIGHT TOE INJURY

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)

22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SECOND METATARSAL REPLACEMENT
Narrative	DUE TO MULTIPLE RIGHT FOOT FRACTURES THE SUBJECT HAS UNDERGONE SEVERAL SUGERIES.
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) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

AEID

Adverse event

RIGHT ROTATOR CUFF TEAR

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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 (7)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

AEID

Adverse event

RIGHT 2ND TOE  
STAPHALOCOCCUS  
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)

22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 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 ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

AEID

Adverse event

ACUTE KIDNEY INJURY

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)

03 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)

05 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

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

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:04:00

---

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

Yes ☒

No ☐

---

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

---

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 00:55:16

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	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)	04 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication CLONAZAPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication ETODOLAC

Prophylaxis Yes ☐  
No ☒

Indication LEFT SHOULDER PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY BILATERAL  
FEET

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	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 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 00:55:16

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Name of Medication IV DRIP  
VANCOMYCIN/ROCEPHIN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT 2ND TOE  
STAPHALOCOCCUS  
INFECTION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 00:55:16

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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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 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)	6 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 (7)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT FOOT PAIN

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	03 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)	06 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 (8)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication AMOXICILLIN/POTASSIUM

Prophylaxis Yes ☐  
No ☒

Indication RIGHT 2ND TOE  
STAPHALOCOCCUS  
INFECTION

Dose per administration 875/125

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	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)	6 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)		13 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) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication DOXYCYCLINE HYCLATE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT 2ND TOE  
STAPHALOCOCCUS  
INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	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)	06 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)	13 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 (11)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication LIDOCAINE PATCH

Prophylaxis Yes ☐  
No ☒

Indication RIGHT 2ND TOE  
STAPHALOCOCCUS  
INFECTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify 1 PATCH DAILY

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) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	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)	6 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)	05 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

Name of Medication DICLOFENAC SODIUM

Prophylaxis Yes ☐  
No ☒

Indication RIGHT 2ND TOE  
STAPHALOCOCCUS  
INFECTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

379 of 2464

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 00:55:16

Generated On: 09 Jun 2021 15:04:00

	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)	6 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)	5 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:04:00

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3092022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Mar 2021 18:17:20

Generated On: 09 Jun 2021 15:04:00

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	SECOND METATARSAL REPLACEMENT	Adverse Event	
15 DEC 2020	RIGHT ROTATOR CUFF REATTACHMENT	Adverse Event	

US3092022

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:04:00

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



US3092022

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:04:00

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 ☐

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/NOV/2020 17:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/NOV/2020 15:54
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

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/NOV/2020 10:42
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

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/DEC/2020 09:28
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

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/APR/2021 15:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 08:42
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



US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:04:00

SAEID	USA-US086-2020-MRNA-1273-P301000004
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	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	75224
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3092022 (Prod: Global Medical Research - M3 Wake Research)

**US3092022**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:04:00**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:05:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'US3092022'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:29:31

US3092022

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:04:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Per source subject had AEs Dizziness and Lethargy, please add to AE log in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:15:16
Query 'Per source subject had AEs Dizziness and Lethargy, please add to AE log in source.' answered with 'has been added ' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 21:01:26
User opened query 'Per source subject had AEs Dizziness and Lethargy, please add to AE log in source.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:45:37
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:27:46
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:32:38

**US3092022**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:27:46
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:29:32

US3092022

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:04:00

[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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:27:46
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:32:38

**US3092022**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'SCRN'	System	05 Aug 2020 18:32:38

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:29:33



**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '57'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'YEARS'	System	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '57'	System	05 Aug 2020 18:35:59

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered 'Male (M)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered 'I'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44



**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:04:00**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:29:56
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:34:44

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:30:46
User entered '5 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:35:59

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Aug 2020'	System	05 Aug 2020 18:35:59



**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2020'	System	05 Aug 2020 18:35:59

US3092022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:04:00

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:35:02
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Please document Protocol Amendment subject enrolled under in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:04:40
Query 'Please document Protocol Amendment subjectdestiny robinson enrolled under in source.' answered with 'confirmed ' (Site from CRA).	(b) (4) (b) (4)	29 Oct 2020 00:41:18
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:41:13
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	21 Oct 2020 20:35:08
User opened query 'Please document Protocol Amendment subject enrolled under in source.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:31:22
DataPoint Un-verified.		13 Aug 2020 18:30:49
DataPoint Verified.		13 Aug 2020 18:30:46
User entered 'Amendment 1 (1)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:35:59

US3092022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:30:46
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:35:59

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:30:46
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:35:59

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:30:46
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:35:59

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:30:46
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:35:59

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:30:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:29:32

**US3092022**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:04:00**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'I'	System	05 Aug 2020 18:36:05



US3092022

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:35:59
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:36:05

US3092022

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:04:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:17:21
User closed query 'The following is still missing from Medical History eCRF page: 2nd metatarsal rod to repair fracture, chronic neck pain due to injury, chronic foot wound, back Pain due to injury, and prostate cancer. Please update. ' (Site from CRA). Query 'The following is still missing from Medical History eCRF page: 2nd metatarsal rod to repair fracture, chronic neck pain due to injury, chronic foot wound, back Pain due to injury, and prostate cancer. Please update. ' answered with 'PREVIOUSLY COMPLETED' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:12:57
Query 'The following is still missing from Medical History eCRF page: 2nd metatarsal rod to repair fracture, chronic neck pain due to injury, chronic foot wound, back Pain due to injury, and prostate cancer. Please update. ' answered with 'PREVIOUSLY COMPLETED' (Site from CRA).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 03:03:06
User opened query 'The following is still missing from Medical History eCRF page: 2nd metatarsal rod to repair fracture, chronic neck pain due to injury, chronic foot wound, back Pain due to injury, and prostate cancer. Please update. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:28:19
User closed query 'Review Medical History and add all medical history to EDC, Fracture Repair, Neck Pain due to injury, etc..' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:28:19
Query 'Review Medical History and add all medical history to EDC, Fracture Repair, Neck Pain due to injury, etc..' answered with 'confirmed ' (Site from CRA).	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:20:13
User opened query 'Review Medical History and add all medical history to EDC, Fracture Repair, Neck Pain due to injury, etc..' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:37:48
DataPoint Verified.		14 Oct 2020 15:36:45
Query 'Subject reported new medical history of foot injury and Back injury, please add to medical history in EDC and source.' canceled (Site from CRA).		14 Oct 2020 15:36:40
User opened query 'Subject reported new medical history of foot injury and Back injury, please add to medical history in EDC and source.' (Site from CRA).		14 Oct 2020 15:26:14
User closed query 'Per source subject has medical history, please answer yes and then add Medical History.' (Site from CRA).		14 Oct 2020 15:23:58

US3092022

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:04:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:30:10
Query 'Per source subject has medical history, please answer yes and then add Medical History.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4)	22 Sep 2020 20:50:01
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'Updated' (Site from DM).	Heather Jimenez (b) (4)	22 Sep 2020 20:49:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:46:07
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:39:24
User opened query 'Per source subject has medical history, please answer yes and then add Medical History.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:32:31
User entered 'No (N)'	Robert Miranda (b) (4)	10 Aug 2020 14:38:07

US3092022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:04:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:47:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:47:48
Data point term sent to Coder	System	22 Sep 2020 20:47:16
User entered 'Hyperlipidemia'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:46:59

US3092022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 00:56:55
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:40
User entered 'UN UNK 2018'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:42
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:43
User entered 'Yes (Y)'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 00:52:00
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:46
User entered empty.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:46:59



US3092022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:04:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 00:52:13
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:05:49
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2018'	System	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2018'	System	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:46:59

**US3092022**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:46:59

US3092022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:01
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:48:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:48:50
Data point term sent to Coder	System	22 Sep 2020 20:48:18
User entered 'Hypertension'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:03
User entered 'UN UNK 2018'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:04
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:27



**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:05
User entered 'Yes (Y)'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:07
User entered empty.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:09
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2018'	System	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2018'	System	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:47:27

**US3092022**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:47:27

US3092022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:15
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:48:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:48:51
Data point term sent to Coder	System	22 Sep 2020 20:48:19
User entered 'Anxiety'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:52



**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:17
User entered 'UN UNK 2017'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:18
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:20
User entered 'Yes (Y)'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:22
User entered empty.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:23
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2017'	System	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2017'	System	22 Sep 2020 20:47:52

**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:47:52



**US3092022**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:47:52

US3092022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:45:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:45:02
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:35:53
Data point term sent to Coder	System	29 Mar 2021 13:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 13:18:01
Coding entries removed.		29 Mar 2021 13:18:01
Signature has been broken.		29 Mar 2021 13:18:01
User entered 'LEFT SHOULDER SURGERY (DUE TO INJURY)' reason for change: Data Entry Error		29 Mar 2021 13:18:01
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:06:29
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 20:49:07
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'confirmed' (Site from DM).	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:20:55
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:34:04

US3092022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:49:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:49:51
Data point term sent to Coder	System	22 Sep 2020 20:49:21
User entered 'Left Shoulder Surgery'	Heather Jimenez (b) (4)	22 Sep 2020 20:48:39
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:32
User entered 'UN UNK 2012'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:34
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:38
User entered 'No (N)'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:40
User entered 'UN UNK 2012'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:42
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:48:39



**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2012'	System	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2012'	System	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2012'	System	22 Sep 2020 20:48:39

**US3092022**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2012'	System	22 Sep 2020 20:48:39

US3092022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:36:05
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory peripheral neuropathy - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Mar 2021 00:09:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 00:09:02
Data point term sent to Coder	System	12 Mar 2021 00:08:02
Coding entries removed.	(b) (4), (b) (6)	12 Mar 2021 00:07:31
Signature has been broken.		12 Mar 2021 00:07:31
User entered 'SENSORY NEUROPATHY BILATERAL FEET' reason for change: Data Entry Error		12 Mar 2021 00:07:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Per CDM (CLR Re-query): Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:53
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:00:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 02:00:23
Data point term sent to Coder	System	25 Nov 2020 01:58:49

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Query 'Per CDM (CLR Re-query): Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'CONFIRMED AND CORRECTED.' (Site from DM).	Vicki Martinez (b) (4)	25 Nov 2020 01:58:09
DataPoint Un-verified.	(b) (4)	
Coding entries removed.	Vicki Martinez (b) (4)	25 Nov 2020 01:57:58
	(b) (4)	
User entered 'SENSORY NEUROPATHY' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 01:57:58
User opened query 'Per CDM (CLR Re-query): Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:39:19
User closed query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:06:50
Query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'will collect at next contact ' (Site from DM).	destiny robinson (b) (4)	29 Oct 2020 00:24:13
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify the type of the NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:47:17
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:51:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	22 Sep 2020 20:51:53
Data point term sent to Coder	System	22 Sep 2020 20:50:23
User entered 'Neuropathy'	Heather Jimenez (b) (4)	22 Sep 2020 20:49:35
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:54
User entered 'UN UNK 2016'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:49:35



**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:55
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:57
User entered 'Yes (Y)'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:06:58
User entered empty.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:00
User entered '0'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2016'	System	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2016'	System	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:49:35

**US3092022**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	22 Sep 2020 20:49:35



US3092022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:36:17
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Dec 2020 16:46:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:46:51
Data point term sent to Coder	System	02 Dec 2020 16:45:53
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 16:45:22
Coding entries removed.		02 Dec 2020 16:45:22
User entered 'PROSTATECTOMY' reason for change: Data Entry Error		02 Dec 2020 16:45:22
DataPoint Verified.		18 Nov 2020 17:07:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:15:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:15:47
Data point term sent to Coder	System	29 Oct 2020 00:21:46
User entered 'Left Shoulder injury/pain'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:21:30

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Apr 2021 15:06:16
Signature has been broken.		10 Apr 2021 15:06:16
User entered 'UN UNK 2010' reason for change:		10 Apr 2021 15:06:16
Data Entry Error		
DataPoint Verified.		30 Mar 2021 16:36:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:45:22
User entered empty; reason for change Data Entry		02 Dec 2020 16:45:22
Error		
DataPoint Verified.		18 Nov 2020 17:07:15
User entered 'un UNK 2012'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:21:30

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Apr 2021 15:06:16
Signature has been broken.		10 Apr 2021 15:06:16
User entered '0' reason for change: Data Entry Error		10 Apr 2021 15:06:16
DataPoint Verified.		30 Mar 2021 16:36:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:45:22
User entered '1' reason for change: Data Entry Error		02 Dec 2020 16:45:22
DataPoint Verified.		18 Nov 2020 17:07:16
User entered '0'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:21:30

**US3092022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:18
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:21:30

**US3092022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:36:23
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:45:22
User entered empty; reason for change Data Entry Error		02 Dec 2020 16:45:22
DataPoint Verified.		18 Nov 2020 17:07:20
User entered 'un UNK 2012'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:21:30

US3092022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:04:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:36:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:45:22
User entered '1' reason for change: Data Entry Error		02 Dec 2020 16:45:22
DataPoint Verified.		18 Nov 2020 17:07:23
User entered '0'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:21:30

**US3092022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2010'	System	10 Apr 2021 15:06:16
User entered empty.	System	02 Dec 2020 16:45:22
User entered 'Jan 2012'	System	29 Oct 2020 00:21:30

**US3092022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2010'	System	10 Apr 2021 15:06:16
User entered empty.	System	02 Dec 2020 16:45:22
User entered '2012'	System	29 Oct 2020 00:21:30



**US3092022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	02 Dec 2020 16:45:22
User entered 'Jan 2012'	System	29 Oct 2020 00:21:30

**US3092022**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	02 Dec 2020 16:45:22
User entered '2012'	System	29 Oct 2020 00:21:30

US3092022

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:36:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Insertion of surgical hardware - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:40
Data point term sent to Coder	System	29 Mar 2021 13:22:48
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 13:21:48
Coding entries removed.		29 Mar 2021 13:21:48
Signature has been broken.		29 Mar 2021 13:21:48
User entered 'RIGHT METATARSAL ROD TO REPAIR FRACTURE' reason for change: Data Entry Error		29 Mar 2021 13:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:27:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:27:06
Data point term sent to Coder	System	24 Nov 2020 06:26:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:26:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:26:12

US3092022

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) Fractured metatarsal 2) METATARSAL ROD TO REPAIR FRACTURE etc.' canceled (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:26:04
	(b) (4), (b) (6)	18 Nov 2020 17:07:39
User opened query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) Fractured metatarsal 2) METATARSAL ROD TO REPAIR FRACTURE etc.' (Site from System). Data point term sent to Coder	Coder Import (b) (4) (b) (4)	16 Nov 2020 12:53:42
User entered '2nd metatarsal rod to repair fracture'	System destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:27:34 12 Nov 2020 20:26:56

US3092022

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:36:39
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:43:59
User entered 'UN UNK 2015' reason for change:		02 Dec 2020 16:43:59
Data Entry Error		
DataPoint Verified.		18 Nov 2020 17:07:45
User entered 'un UNK 2020'	destiny robinson (b) (4)	12 Nov 2020 20:26:56
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:47
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:26:56

US3092022

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:04:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:36:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:43:59
User entered 'No (N)' reason for change: Data Entry Error		02 Dec 2020 16:43:59
DataPoint Verified.		18 Nov 2020 17:07:50
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:26:56

**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:36:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:43:59
User entered 'UN UNK 2015' reason for change: Data Entry Error		02 Dec 2020 16:43:59
DataPoint Verified.		18 Nov 2020 17:07:52
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:26:56



**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:07:54
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:26:56

**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2015'	System	02 Dec 2020 16:43:59
User entered 'Jan 2020'	System	12 Nov 2020 20:26:56

**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2015'	System	02 Dec 2020 16:43:59
User entered '2020'	System	12 Nov 2020 20:26:56

**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2015'	System	02 Dec 2020 16:43:59
User entered empty.	System	12 Nov 2020 20:26:56

**US3092022**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2015'	System	02 Dec 2020 16:43:59
User entered empty.	System	12 Nov 2020 20:26:56

US3092022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:36:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Neck injury, LLT: Neck injury - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Nov 2020 06:42:04
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	System	25 Nov 2020 19:04:09
	Vicki Martinez (b) (4)	25 Nov 2020 19:03:44
Coding entries removed.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 19:03:44
User entered 'CHRONIC NECK PAIN DUE TO INJURY' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Vicki Martinez (b) (4)	25 Nov 2020 19:03:44
	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:08:22
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: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 20:30:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 20:30:33
Data point term sent to Coder	(b) (4)	
User entered 'chronic neck pain'	System	12 Nov 2020 20:29:38
	destiny robinson (b) (4)	12 Nov 2020 20:29:15
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:24
User entered 'un UNK 2017'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:26
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:29:15



**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:28
User entered 'Yes (Y)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:30
User entered empty.	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:08:32
User entered '0'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2017'	System	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2017'	System	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	12 Nov 2020 20:29:15

**US3092022**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	12 Nov 2020 20:29:15

US3092022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:36:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Site specific injuries NEC, LLT: Back injury - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Nov 2020 22:10:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 22:10:24
Data point term sent to Coder	System	25 Nov 2020 19:03:08
User entered 'Back Pain due to injury'	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:02:51



**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'un UNK 2017'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:05
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:07
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:09
User signature succeeded.	Valentine Ebu (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2017'	System	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2017'	System	25 Nov 2020 19:02:51

**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	25 Nov 2020 19:02:51



**US3092022**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	25 Nov 2020 19:02:51

US3092022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Apr 2021 11:09:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:09:29
Data point term sent to Coder	System	10 Apr 2021 15:02:56
User entered 'HISTORY OF DIZZINESS SECONDARY TO NECK INJURY SUSTAINED IN MILITARY' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Apr 2021 15:02:36
Data point term sent to Coder	System	09 Apr 2021 21:23:34
User closed query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) DIZZINESS SECONDARY 2) INJURY SUSTAINED IN MILITARY etc. ' (Site from System).	System	09 Apr 2021 21:22:42
Query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) DIZZINESS SECONDARY 2) INJURY SUSTAINED IN MILITARY etc. ' answered with 'MEDICAL HISTORY UPDATED IN ECRF AND SOURCE. ' (Site from System).	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:22:42
Data point term sent to Coder	System	09 Apr 2021 21:21:31
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:20:32
Signature has been broken.	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:20:32
User entered 'DIZZINESS SECONDARY TO NECK INJURY' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:20:32
User opened query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) DIZZINESS SECONDARY 2) INJURY SUSTAINED IN MILITARY etc.	Coder Import (b) (4) (b) (4)	02 Apr 2021 09:40:23

US3092022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:04:00

[Condition](#)

Audit	User	Time (GMT)
' (Site from System).		
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 16:37:31
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
Data point term sent to Coder	(b) (4)	12 Mar 2021 01:02:25
Coding entries removed.	System	12 Mar 2021 01:01:35
Signature has been broken.	(b) (4), (b) (6)	12 Mar 2021 01:01:35
User entered 'HISTORY OF DIZZINESS SECONDARY TO INJURY SUSTAINED IN MILITARY' reason for change: Data Entry Error		12 Mar 2021 01:01:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 22:37:35
Data point term sent to Coder	(b) (4)	25 Nov 2020 22:37:35
User entered 'history of dizziness'	System	25 Nov 2020 19:30:49
	Vicki Martinez (b) (4)	25 Nov 2020 19:30:06
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:33
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'Un UNK 2017' reason for change: Data Entry Error	System	25 Nov 2020 19:30:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Vicki Martinez (b) (4)	25 Nov 2020 19:30:20
User entered 'u UNK 2017' (non-conformant).	(b) (4)	
	System	25 Nov 2020 19:30:06
	Vicki Martinez (b) (4)	25 Nov 2020 19:30:06
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:34
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:06

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:06

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:06

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:39
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:06



**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2017'	System	25 Nov 2020 19:30:20
User entered empty.	System	25 Nov 2020 19:30:06

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2017'	System	25 Nov 2020 19:30:20
User entered empty.	System	25 Nov 2020 19:30:06

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	25 Nov 2020 19:30:06

**US3092022**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	25 Nov 2020 19:30:06

US3092022

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 19:32:19
Data point term sent to Coder	(b) (4)	
User entered 'left shoulder injury'	Coder Import (b) (4)	25 Nov 2020 19:32:19
	System	25 Nov 2020 19:31:52
	Vicki Martinez (b) (4)	25 Nov 2020 19:30:58
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:55
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'un UNK 2012'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:58

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:58

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:37:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 19:31:24
User entered 'Yes (Y)'	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 19:30:58
	(b) (4)	



**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:00
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'un UNK 2012' reason for change:	(b) (4)	
Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:31:24
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 19:30:58
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:30:58

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2012'	System	25 Nov 2020 19:30:58

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2012'	System	25 Nov 2020 19:30:58

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2012'	System	25 Nov 2020 19:31:24
User entered empty.	System	25 Nov 2020 19:30:58

**US3092022**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2012'	System	25 Nov 2020 19:31:24
User entered empty.	System	25 Nov 2020 19:30:58

US3092022

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:12
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:50:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:50:15
Data point term sent to Coder	System	29 Mar 2021 13:26:53
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 13:26:38
Signature has been broken.		29 Mar 2021 13:26:38
User entered 'LEFT SHOULDER PAIN DUE TO INJURY' reason for change: Data Entry Error		29 Mar 2021 13:26:38
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:23:35
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: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 19:33:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 19:33:37
Data point term sent to Coder	System	25 Nov 2020 19:32:53
User entered 'left shoulder pain'	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:14
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'un Dec 2012'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:32:47



**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:16
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:18
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Dec 2012'	System	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2012'	System	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	25 Nov 2020 19:32:47

**US3092022**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	25 Nov 2020 19:32:47



US3092022

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Dec 2020 16:48:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:48:31
Data point term sent to Coder	System	02 Dec 2020 16:46:54
User entered 'PROSTATE CANCER'	(b) (4), (b) (6)	02 Dec 2020 16:46:01

US3092022

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Apr 2021 15:05:22
Signature has been broken.		10 Apr 2021 15:05:22
User entered 'UN UNK 2010' reason for change:		10 Apr 2021 15:05:22
Data Entry Error		
DataPoint Verified.		30 Mar 2021 16:38:29
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:46:01

US3092022

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:04:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	10 Apr 2021 15:05:22
Signature has been broken.		10 Apr 2021 15:05:22
User entered '0' reason for change: Data Entry Error		10 Apr 2021 15:05:22
DataPoint Verified.		30 Mar 2021 16:38:31
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '1'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:46:01

**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:33
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:46:01

**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:46:01

**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'l'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 16:46:01

**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2010'	System	10 Apr 2021 15:05:22
User entered empty.	System	02 Dec 2020 16:46:01

**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2010'	System	10 Apr 2021 15:05:22
User entered empty.	System	02 Dec 2020 16:46:01



**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	02 Dec 2020 16:46:01

**US3092022**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	02 Dec 2020 16:46:01

US3092022

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:04:00

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:44
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Wound, LLT: Surgical wound - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 05:32:39
	(b) (4)	
	Coder Import (b) (4)	18 Mar 2021 05:32:39
	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 23:47:42
User entered 'CHRONIC RIGHT FOOT WOUND (S/P MULTIPLE SURGERIES)'	(b) (4), (b) (6)	11 Mar 2021 23:47:21

US3092022

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:46
Signature has been broken.		29 Mar 2021 14:52:02
User entered 'UN UNK 2015' reason for change: Data Entry Error		29 Mar 2021 14:52:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:47:21

US3092022

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:49
Signature has been broken.		29 Mar 2021 14:52:02
User entered '0' reason for change: Data Entry Error		29 Mar 2021 14:52:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:47:21

**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:47:21

**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:57
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:47:21

**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:38:58
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:47:21



**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2015'	System	29 Mar 2021 14:52:02
User entered empty.	System	11 Mar 2021 23:47:21

**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2015'	System	29 Mar 2021 14:52:02
User entered empty.	System	11 Mar 2021 23:47:21

**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	11 Mar 2021 23:47:21

**US3092022**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	11 Mar 2021 23:47:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.	(b) (4)	30 Mar 2021 16:39:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	12 Mar 2021 01:26:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 01:26:02
Data point term sent to Coder	System	12 Mar 2021 01:11:26
Coding entries removed.	(b) (4), (b) (6)	12 Mar 2021 01:11:03
User entered 'BRADYCARDIA' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 01:11:03
Data point term sent to Coder	System	12 Mar 2021 01:10:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Mar 2021 01:10:02
Data point term sent to Coder	System	12 Mar 2021 00:52:21
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Mar 2021 00:52:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 23:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 23:56:56
Data point term sent to Coder	System	11 Mar 2021 23:55:53
User entered 'PROSTATECTOMY'	(b) (4), (b) (6)	11 Mar 2021 23:55:21

**US3092022**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:39:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'UN UNK 2017' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 01:11:03
DataPoint activated with code reason code Data required.		12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered empty.		11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:39:23
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 01:11:03
DataPoint activated with code reason code Data required.		12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered '1'		11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:39:24
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Mar 2021 01:11:03
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 01:10:02
		12 Mar 2021 00:52:00
User entered 'No (N)'		11 Mar 2021 23:55:21



**US3092022**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:39:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered empty.		11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		30 Mar 2021 16:39:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Mar 2021 01:11:03
DataPoint activated with code reason code Data required.		12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered '1'		11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2017'	System	12 Mar 2021 01:11:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered empty.	System	11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2017'	System	12 Mar 2021 01:11:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered empty.	System	11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint activated with code reason code Data required.		12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered empty.	System	11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint activated with code reason code Data required.		12 Mar 2021 01:10:02
DataPoint inactivated with code reason code Data not required.		12 Mar 2021 00:52:00
User entered empty.	System	11 Mar 2021 23:55:21

US3092022

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:39:41
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:55:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:55:11
Data point term sent to Coder	System	29 Mar 2021 14:53:44
User entered 'RIGHT FOOT FRACTURE'	(b) (4), (b) (6)	29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:39:51
User entered 'UN UNK 2015'		29 Mar 2021 14:52:58



**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:39:53
User entered '0'		29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:39:54
User entered 'No (N)'		29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:39:56
User entered 'UN UNK 2015'		29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:31:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:39:57
User entered '0'		29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2015'	System	29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2015'	System	29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2015'	System	29 Mar 2021 14:52:58

**US3092022**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2015'	System	29 Mar 2021 14:52:58



US3092022

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:04:00

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Site specific injuries NEC, LLT: Neck injury - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 09:39:48
Data point term sent to Coder	(b) (4)	
User entered 'NECK INJURY (SUSTAINED IN MILITARY)'	Coder Import (b) (4)	12 Apr 2021 09:39:48
	System	09 Apr 2021 21:22:33
	Marissa Cervenka (b) (4)	09 Apr 2021 21:21:47
	(b) (4)	

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'UN UNK 2017'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Yes (Y)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
DataPoint Verified.		14 Apr 2021 22:24:15
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'Jan 2017'	System	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '2017'	System	09 Apr 2021 21:21:47



**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	09 Apr 2021 21:21:47

**US3092022**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered empty.	System	09 Apr 2021 21:21:47

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:34:42
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:34:43
User entered '05 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:34:48
User entered '12:10'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered '05 Aug 2020 12:10'	System	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:34:51
User entered '181.5' cm	Robert Miranda (b) (4)	10 Aug 2020 14:42:10
DataPoint set to visible.	(b) (4) System	05 Aug 2020 18:36:05

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:34:54
User entered '115.0' kg	Robert Miranda (b) (4)	10 Aug 2020 14:42:10
DataPoint set to visible.	(b) (4) System	05 Aug 2020 18:36:05



US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
Amendment Manager: User entered '34.90958'	System	16 Sep 2020 23:44:22
User entered '34.9'	System	10 Aug 2020 14:42:10
DataPoint set to visible.	System	05 Aug 2020 18:36:05

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'kg/m2'	System	10 Aug 2020 14:42:10
DataPoint set to visible.	System	05 Aug 2020 18:36:05

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:44:04
User closed query 'Please mark not done for temperature, pulse, respiratory, SBP, and DBP as subject was screened and randomized on the same day.' (Site from CRA).		23 Sep 2020 15:57:01
Query 'Please mark not done for temperature, pulse, respiratory, SBP, and DBP as subject was screened and randomized on the same day.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:36
User opened query 'Please mark not done for temperature, pulse, respiratory, SBP, and DBP as subject was screened and randomized on the same day.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:35:47
User entered '36.8' C	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:06:14
Query 'Please insert "ND-Not Done". Data is required for this field to be verified. ' canceled (Site from CRA).		08 Oct 2020 19:06:11
User opened query 'Please insert "ND-Not Done". Data is required for this field to be verified. ' (Site from CRA).		02 Oct 2020 17:44:29
User entered empty; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:36
User entered 'Oral (Oral)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:06:15
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:36
User entered '50'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'bpm'	System	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:37:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:36
User entered '14'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10



US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'breaths/min'	System	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:38:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:36
User entered '143'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'mmHg'	System	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:38:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:40:36
User entered '82'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:42:10

**US3092022**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User entered 'mmHg'	System	10 Aug 2020 14:42:10

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52

US3092022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52

US3092022

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:34:20
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:43:04



US3092022

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:43:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:37:12
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:34:20
User entered '05 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:43:04

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

[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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

[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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08



US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

[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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Robert Miranda (b) (4)	10 Aug 2020 14:46:14
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	Vicki Martinez (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08



US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

**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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

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 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered '0'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered 'I'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

**US3092022**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:04:00**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '0'	Vicki Martinez (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:04:00

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:52:52
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:33:53
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:41:08

US3092022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:04:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:39:31
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:44:52

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:39:31
User entered '5 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:44:52



**US3092022**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[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 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:39:31
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:44:52

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'VISIT1'	System	05 Aug 2020 18:44:52

US3092022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:39:19

US3092022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:00

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:18:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:18:38
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:40:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 18:39:19
User entered '101068' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:39:19

US3092022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:00

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 18:39:19

US3092022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:00

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 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:45:29

US3092022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:00

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 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:45:29

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:04:00**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:45:29



**US3092022**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:04:00**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:45:29

US3092022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:04:00

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:40:09
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:45:29

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:33:57
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' (Site from CRA).		23 Oct 2020 15:47:51
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:24:17
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:23:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:23:59
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:42
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:30
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:23
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:41:24
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:33:56
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' (Site from CRA).		12 Nov 2020 17:33:54
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4)	26 Oct 2020 19:51:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4)	26 Oct 2020 19:50:49
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:48:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 15:47:40
DataPoint Verified.		13 Aug 2020 18:41:26
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:33:57
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' (Site from CRA).		23 Oct 2020 15:47:51
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:24:17
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:23:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:23:59
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:42
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:30
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:23
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:41:24
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:33:56
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' (Site from CRA).		12 Nov 2020 17:33:54
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4)	26 Oct 2020 19:51:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4)	26 Oct 2020 19:50:49
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:48:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 15:47:40
DataPoint Verified.		13 Aug 2020 18:41:26
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User accepted default value 'Pre-Dose (PREDOSE)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered '05 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 14:53:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Aug 2020 14:53:17
User entered '12:10' reason for change: Data Entry Error	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:53:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Aug 2020 14:52:57
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered '05 Aug 2020 12:10'	System	10 Aug 2020 14:53:17
User entered empty.	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered '36.8' C	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered 'Oral (Oral)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered '50'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'bpm'	System	10 Aug 2020 14:52:57



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered '14'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'breaths/min'	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered '143'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'mmHg'	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered '82'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'mmHg'	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:00

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:33:57
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' (Site from CRA).		23 Oct 2020 15:47:51
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:24:17
DataPoint Un-verified.	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:23:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	15 Oct 2020 16:23:59
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:34:42
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day.' canceled (Site from CRA).		23 Sep 2020 16:34:30
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day.' (Site from CRA).		23 Sep 2020 16:34:23
DataPoint Verified.		13 Aug 2020 18:41:24
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:04:00

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:33:56
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' (Site from CRA).		12 Nov 2020 17:33:54
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4)	26 Oct 2020 19:51:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Marissa Cervenka (b) (4)	26 Oct 2020 19:50:49
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 15:48:01
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 15:47:40
DataPoint Verified.		13 Aug 2020 18:41:26
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User accepted default value 'Post-Dose (POSTDOSE)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:35
User closed query 'Please change answer to Yes and add post dose vitals. ' (Site from CRA).		23 Oct 2020 15:48:42
Query 'Please change answer to Yes and add post dose vitals. ' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:42:32
DataPoint Un-verified.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:42:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User opened query 'Please change answer to Yes and add post dose vitals. ' (Site from CRA).		13 Aug 2020 18:41:16
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 14:53:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 14:53:17
User entered 'No (N)' reason for change: Data Entry Error	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:53:17
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 14:52:57
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:38
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '5 Aug 2020' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:40
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '14:31' reason for change: Data Entry Error	(b) (4) Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered '5 Aug 2020 14:31'	System	22 Sep 2020 20:42:22
User entered empty.	System	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:44
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '98.4' F reason for change: Data Entry Error	(b) (4) Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:46
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57
	(b) (4)	

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:52:57



US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:48
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '55' reason for change: Data Entry Error	(b) (4) Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'bpm'	System	22 Sep 2020 20:42:22
User entered empty.	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:34:51
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '14' reason for change: Data Entry Error	(b) (4) Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'breaths/min'	System	22 Sep 2020 20:42:22
User entered empty.	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:35:00
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '147' reason for change: Data Entry Error	(b) (4) Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'mmHg'	System	22 Sep 2020 20:42:22
User entered empty.	System	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:35:04
DataPoint Un-verified.	Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
User entered '80' reason for change: Data Entry Error	(b) (4) Heather Jimenez (b) (4)	22 Sep 2020 20:42:22
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:42:50
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 14:52:57

US3092022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'mmHg'	System	22 Sep 2020 20:42:22
User entered empty.	System	10 Aug 2020 14:52:57



US3092022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:48:37
User closed query 'Please change to No, as PE is only recorded under screening visit for subjects who complete screening and Day 1 visits on the same day.' (Site from CRA).		23 Sep 2020 15:57:23
Query 'Please change to No, as PE is only recorded under screening visit for subjects who complete screening and Day 1 visits on the same day.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:39:41
User entered 'No (N)' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:39:33
User opened query 'Please change to No, as PE is only recorded under screening visit for subjects who complete screening and Day 1 visits on the same day.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:38:14
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:53:36

US3092022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:48:39
User entered empty; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:39:33
User entered '05 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:53:36

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:43:19
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:43:21
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

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 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:43:22
User entered empty.	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:43:24
User entered '5 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:43:28
User entered '13:40'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:46:53



**US3092022**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:00**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered '5 Aug 2020 13:40'	System	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:43:30
User entered 'Left Arm (LEFT ARM)'	Vicki Martinez (b) (4) (b) (4)	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User closed query 'Please document in source frequency of the study treatment dosing.' (Site from CRA).		12 Nov 2020 17:40:58
Query 'Please document in source frequency of the study treatment dosing.' answered with 'confirmed ' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 21:03:26
User opened query 'Please document in source frequency of the study treatment dosing.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:44:02
DataPoint Verified.		13 Aug 2020 18:43:36
User entered 'ONCE'	System	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 18:46:53

US3092022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:25
User closed query 'Per source, Immunogenicity Assessment was completed, please update.' (Site from CRA).		12 Nov 2020 17:42:22
User closed query 'Immunogenicity Assessment is required for Day 1, please review. Lab Documentation is not filed in source.' (Site from CRA).		12 Nov 2020 17:42:15
Query 'Per source, Immunogenicity Assessment was completed, please update.' answered with 'confirmed' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:58
Query 'Immunogenicity Assessment is required for Day 1, please review. Lab Documentation is not filed in source.' answered with 'confirmed' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:51
User entered 'Yes (Y)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:45
User opened query 'Per source, Immunogenicity Assessment was completed, please update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:01:08
User opened query 'Immunogenicity Assessment is required for Day 1, please review. Lab Documentation is not filed in source.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:48:14
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:55:58

US3092022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:27
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:44:25
User entered '5 Aug 2020' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:44:25
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:43:45
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:55:58

US3092022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:30
User entered '13:34' reason for change: Data Entry Error	destiny robinson (b) (4)	27 Oct 2020 20:44:33
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Oct 2020 20:44:25
User entered '13:30' reason for change: Data Entry Error	System	27 Oct 2020 20:44:25
User opened query 'Data is required. Please provide.' (Site from System).	destiny robinson (b) (4)	27 Oct 2020 20:43:45
User entered empty.	(b) (4)	27 Oct 2020 20:43:45
	Robert Miranda (b) (4)	10 Aug 2020 14:55:58
	(b) (4)	

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered '5 Aug 2020 13:34'	System	27 Oct 2020 20:44:33
User entered '5 Aug 2020 13:30'	System	27 Oct 2020 20:44:25
User entered empty.	System	10 Aug 2020 14:55:58



US3092022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:04:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:45
User closed query 'Per Source, Nasal Swab Collection was completed, please update.' (Site from CRA).		12 Nov 2020 17:42:43
User closed query 'Nasal Swab is required for Day 1, please review. Lab Documentation is not filed in source.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 17:42:41
Query 'Per Source, Nasal Swab Collection was completed, please update.' answered with 'confirmed' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:33
Query 'Nasal Swab is required for Day 1, please review. Lab Documentation is not filed in source.' answered with 'confirmed' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:28
User entered '5 Aug 2020' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:06
User opened query 'Per Source, Nasal Swab Collection was completed, please update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:04:20
User opened query 'Nasal Swab is required for Day 1, please review. Lab Documentation is not filed in source.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:49:04
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:56:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:04:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:56:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:04:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:51
User entered 'Yes (Y)' reason for change: Data Entry Error	destiny robinson (b) (4)	27 Oct 2020 20:43:06
User entered 'No (N)'	(b) (4) Robert Miranda (b) (4)	10 Aug 2020 14:56:08

US3092022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:04:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:53
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 20:43:19
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	27 Oct 2020 20:43:19
User entered '13:30' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	27 Oct 2020 20:43:19
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 20:43:06
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:56:08

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered '5 Aug 2020 13:30'	System	27 Oct 2020 20:43:19
User entered empty.	System	10 Aug 2020 14:56:08

US3092022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:04:00

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:56:08

US3092022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:04:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:56
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:56:08

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:00**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:42:58
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 14:56:08



**US3092022**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered empty.	System	10 Aug 2020 14:56:08

US3092022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:04:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:13:19
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	14 Aug 2020 19:22:32

**US3092022**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'I'	System	14 Aug 2020 19:22:32

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:32:43', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '56b9aba2-6b3d-4560-af00-b53ace335bb0'	System	05 Aug 2020 19:33:36
User entered 'Yes (Y)'	System	05 Aug 2020 19:33:36

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:32:51', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '56b9aba2-6b3d-4560-af00-b53ace335bb0'	System	05 Aug 2020 19:33:36
User entered '97.5'	System	05 Aug 2020 19:33:36

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:32:59', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '56b9aba2-6b3d-4560-af00-b53ace335bb0'	System	05 Aug 2020 19:33:36
User entered 'No (N)'	System	05 Aug 2020 19:33:36

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:33:31', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '56b9aba2-6b3d-4560-af00-b53ace335bb0'	System	05 Aug 2020 19:33:36
User entered '05 Aug 2020 14:33'	System	05 Aug 2020 19:33:36



US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 14:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 16:30'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 17:25'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 2'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:35:51', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4d717d7f-7c50-4970-afbb-0f2aa4544a66'	System	06 Aug 2020 18:36:18
User entered 'Yes (Y)'	System	06 Aug 2020 18:36:18

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:36:02', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4d717d7f-7c50-4970-afbb-0f2aa4544a66'	System	06 Aug 2020 18:36:18
User entered '97.5'	System	06 Aug 2020 18:36:18

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:36:08', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4d717d7f-7c50-4970-afbb-0f2aa4544a66'	System	06 Aug 2020 18:36:18
User entered 'No (N)'	System	06 Aug 2020 18:36:18

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:36:14', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4d717d7f-7c50-4970-afbb-0f2aa4544a66'	System	06 Aug 2020 18:36:18
User entered '06 Aug 2020 13:36'	System	06 Aug 2020 18:36:18



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 3'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:38:02', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e330cebe-8d90-4717-a150-c43daab4faf6'	System	08 Aug 2020 13:38:27
User entered 'Yes (Y)'	System	08 Aug 2020 13:38:27

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:38:11', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e330cebe-8d90-4717-a150-c43daab4faf6'	System	08 Aug 2020 13:38:27
User entered '97.5'	System	08 Aug 2020 13:38:27

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:38:20', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e330cebe-8d90-4717-a150-c43daab4faf6'	System	08 Aug 2020 13:38:27
User entered 'No (N)'	System	08 Aug 2020 13:38:27

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:38:23', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e330cebe-8d90-4717-a150-c43daab4faf6'	System	08 Aug 2020 13:38:27
User entered '08 Aug 2020 08:38'	System	08 Aug 2020 13:38:27

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:46:53



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 4'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 5'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:06:56', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ee2d1a59-b909-42b4-922b-bb3588e72b8a'	System	10 Aug 2020 03:07:33
User entered 'Yes (Y)'	System	10 Aug 2020 03:07:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:07:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ee2d1a59-b909-42b4-922b-bb3588e72b8a'	System	10 Aug 2020 03:07:33
User entered '97.6'	System	10 Aug 2020 03:07:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:07:24', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ee2d1a59-b909-42b4-922b-bb3588e72b8a'	System	10 Aug 2020 03:07:33
User entered 'No (N)'	System	10 Aug 2020 03:07:33

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:07:30', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ee2d1a59-b909-42b4-922b-bb3588e72b8a'	System	10 Aug 2020 03:07:33
User entered '09 Aug 2020 22:07'	System	10 Aug 2020 03:07:33

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:46:53



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 6'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:40:52', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '009956c8-4af5-4962-9b1b-c1e40947a7a5'	System	11 Aug 2020 03:41:19
User entered 'Yes (Y)'	System	11 Aug 2020 03:41:19

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:06', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '009956c8-4af5-4962-9b1b-c1e40947a7a5'	System	11 Aug 2020 03:41:19
User entered '97.5'	System	11 Aug 2020 03:41:19

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:12', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '009956c8-4af5-4962-9b1b-c1e40947a7a5'	System	11 Aug 2020 03:41:19
User entered 'No (N)'	System	11 Aug 2020 03:41:19

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:16', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '009956c8-4af5-4962-9b1b-c1e40947a7a5'	System	11 Aug 2020 03:41:19
User entered '10 Aug 2020 22:41'	System	11 Aug 2020 03:41:19

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:46:53



US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 7'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:08:59', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2d5b9209-edfc-43f9-aa23-14349a276027'	System	12 Aug 2020 14:09:18
User entered 'Yes (Y)'	System	12 Aug 2020 14:09:18

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:07', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2d5b9209-edfc-43f9-aa23-14349a276027'	System	12 Aug 2020 14:09:18
User entered '97.4'	System	12 Aug 2020 14:09:18

US3092022

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:12', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2d5b9209-edfc-43f9-aa23-14349a276027'	System	12 Aug 2020 14:09:18
User entered 'No (N)'	System	12 Aug 2020 14:09:18

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:15', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2d5b9209-edfc-43f9-aa23-14349a276027'	System	12 Aug 2020 14:09:18
User entered '12 Aug 2020 09:09'	System	12 Aug 2020 14:09:18

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:46:53



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:34:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5b8a6d19-fe85-447c-9406-5e6986bf8e38'	System	05 Aug 2020 19:34:25
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 19:34:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:34:05', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5b8a6d19-fe85-447c-9406-5e6986bf8e38'	System	05 Aug 2020 19:34:25
User entered 'No (N)'	System	05 Aug 2020 19:34:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:34:08', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5b8a6d19-fe85-447c-9406-5e6986bf8e38'	System	05 Aug 2020 19:34:25
User entered 'No (N)'	System	05 Aug 2020 19:34:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:34:16', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5b8a6d19-fe85-447c-9406-5e6986bf8e38'	System	05 Aug 2020 19:34:25
User entered 'None (1)'	System	05 Aug 2020 19:34:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:34:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5b8a6d19-fe85-447c-9406-5e6986bf8e38'	System	05 Aug 2020 19:34:25
User entered '05 Aug 2020 14:34'	System	05 Aug 2020 19:34:25

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 14:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 16:30'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:46:53



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 17:25'	System	05 Aug 2020 18:46:53



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 2'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:36:32', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6617da7c-4bdc-4c95-a7a7-cb28124ec336'	System	06 Aug 2020 18:37:25
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 18:37:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:36:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6617da7c-4bdc-4c95-a7a7-cb28124ec336'	System	06 Aug 2020 18:37:25
User entered 'No (N)'	System	06 Aug 2020 18:37:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:36:50', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6617da7c-4bdc-4c95-a7a7-cb28124ec336'	System	06 Aug 2020 18:37:25
User entered 'Yes (Y)'	System	06 Aug 2020 18:37:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:37:14', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6617da7c-4bdc-4c95-a7a7-cb28124ec336'	System	06 Aug 2020 18:37:25
User entered '3'	System	06 Aug 2020 18:37:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:37:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6617da7c-4bdc-4c95-a7a7-cb28124ec336'	System	06 Aug 2020 18:37:25
User entered 'None (1)'	System	06 Aug 2020 18:37:25

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:37:22', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6617da7c-4bdc-4c95-a7a7-cb28124ec336'	System	06 Aug 2020 18:37:25
User entered '06 Aug 2020 13:37'	System	06 Aug 2020 18:37:25



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 3'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:39:12', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bd48d14-71a6-4e37-90a0-eaada3a98b0e'	System	08 Aug 2020 13:40:04
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 13:40:04

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:39:20', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bd48d14-71a6-4e37-90a0-eaada3a98b0e'	System	08 Aug 2020 13:40:04
User entered 'No (N)'	System	08 Aug 2020 13:40:04

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:39:51', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bd48d14-71a6-4e37-90a0-eaada3a98b0e'	System	08 Aug 2020 13:40:04
User entered 'No (N)'	System	08 Aug 2020 13:40:04

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:39:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bd48d14-71a6-4e37-90a0-eaada3a98b0e'	System	08 Aug 2020 13:40:04
User entered 'None (1)'	System	08 Aug 2020 13:40:04

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bd48d14-71a6-4e37-90a0-eaada3a98b0e'	System	08 Aug 2020 13:40:04
User entered '08 Aug 2020 08:40'	System	08 Aug 2020 13:40:04



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 4'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 5'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:07:49', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5a5aacff-1587-4bb6-b764-b05828cc9f0b'	System	10 Aug 2020 03:08:22
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 03:08:22

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:07:52', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5a5aacff-1587-4bb6-b764-b05828cc9f0b'	System	10 Aug 2020 03:08:22
User entered 'No (N)'	System	10 Aug 2020 03:08:22

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:07:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5a5aacff-1587-4bb6-b764-b05828cc9f0b'	System	10 Aug 2020 03:08:22
User entered 'No (N)'	System	10 Aug 2020 03:08:22



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:15', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5a5aacff-1587-4bb6-b764-b05828cc9f0b'	System	10 Aug 2020 03:08:22
User entered 'None (1)'	System	10 Aug 2020 03:08:22

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5a5aacff-1587-4bb6-b764-b05828cc9f0b'	System	10 Aug 2020 03:08:22
User entered '09 Aug 2020 22:08'	System	10 Aug 2020 03:08:22

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 6'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:28', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9fccabc9-44b7-4fcf-9922-283ac7f9c218'	System	11 Aug 2020 03:41:52
User entered 'None (1)'	System	11 Aug 2020 03:41:52

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:32', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9fccabc9-44b7-4fcf-9922-283ac7f9c218'	System	11 Aug 2020 03:41:52
User entered 'No (N)'	System	11 Aug 2020 03:41:52

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9fccabc9-44b7-4fcf-9922-283ac7f9c218'	System	11 Aug 2020 03:41:52
User entered 'No (N)'	System	11 Aug 2020 03:41:52



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:43', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9fccabc9-44b7-4fcf-9922-283ac7f9c218'	System	11 Aug 2020 03:41:52
User entered 'None (1)'	System	11 Aug 2020 03:41:52

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:41:48', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9fccabc9-44b7-4fcf-9922-283ac7f9c218'	System	11 Aug 2020 03:41:52
User entered '10 Aug 2020 22:41'	System	11 Aug 2020 03:41:52

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 7'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:29', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2e0eeada-977c-4e66-9fba-142121543c76'	System	12 Aug 2020 14:09:49
User entered 'None (1)'	System	12 Aug 2020 14:09:49

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:32', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2e0eeada-977c-4e66-9fba-142121543c76'	System	12 Aug 2020 14:09:49
User entered 'No (N)'	System	12 Aug 2020 14:09:49

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:36', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2e0eeada-977c-4e66-9fba-142121543c76'	System	12 Aug 2020 14:09:49
User entered 'No (N)'	System	12 Aug 2020 14:09:49



US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:42', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2e0eeada-977c-4e66-9fba-142121543c76'	System	12 Aug 2020 14:09:49
User entered 'None (1)'	System	12 Aug 2020 14:09:49

US3092022

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:45', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2e0eeada-977c-4e66-9fba-142121543c76'	System	12 Aug 2020 14:09:49
User entered '12 Aug 2020 09:09'	System	12 Aug 2020 14:09:49

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:07', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'No interference with activity (1)'	System	05 Aug 2020 19:35:52

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:14', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'No interference with activity (1)'	System	05 Aug 2020 19:35:52

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:21', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'No interference with activity (1)'	System	05 Aug 2020 19:35:52



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:25', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'No interference with activity (1)'	System	05 Aug 2020 19:35:52

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:33', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'None (0)'	System	05 Aug 2020 19:35:52

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'None (0)'	System	05 Aug 2020 19:35:52

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:46', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered 'No (N)'	System	05 Aug 2020 19:35:52

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-05T14:35:49', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '227d92b3-0d12-4a66-8512-88488b4d7cb7'	System	05 Aug 2020 19:35:52
User entered '05 Aug 2020 14:35'	System	05 Aug 2020 19:35:52

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 14:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 16:30'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 18:46:53



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Aug 2020 17:25'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 2'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:38:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'None (0)'	System	06 Aug 2020 18:38:21

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:37:58', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'None (0)'	System	06 Aug 2020 18:38:21

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:37:56', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'None (0)'	System	06 Aug 2020 18:38:21

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:38:03', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'None (0)'	System	06 Aug 2020 18:38:21

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:38:06', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'None (0)'	System	06 Aug 2020 18:38:21



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:38:09', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'None (0)'	System	06 Aug 2020 18:38:21

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:38:16', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered 'No (N)'	System	06 Aug 2020 18:38:21

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-06T13:38:18', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3f1114af-5d85-4044-b4a5-1a6afc796d07'	System	06 Aug 2020 18:38:21
User entered '06 Aug 2020 13:38'	System	06 Aug 2020 18:38:21

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 3'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:07', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'None (0)'	System	08 Aug 2020 13:43:06

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:11', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'None (0)'	System	08 Aug 2020 13:43:06



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:16', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'None (0)'	System	08 Aug 2020 13:43:06

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'None (0)'	System	08 Aug 2020 13:43:06

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:23', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'None (0)'	System	08 Aug 2020 13:43:06

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:40:26', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'None (0)'	System	08 Aug 2020 13:43:06

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:42:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered 'No (N)'	System	08 Aug 2020 13:43:06

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-08T08:43:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd8aee7a3-5d37-4c79-82a3-7af411147d09'	System	08 Aug 2020 13:43:06
User entered '08 Aug 2020 08:43'	System	08 Aug 2020 13:43:06

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 18:46:53



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 4'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 5'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:38', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'None (0)'	System	10 Aug 2020 03:09:12

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:41', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'None (0)'	System	10 Aug 2020 03:09:12

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:49', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:09:12

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:54', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'None (0)'	System	10 Aug 2020 03:09:12



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:08:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'None (0)'	System	10 Aug 2020 03:09:12

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:09:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'None (0)'	System	10 Aug 2020 03:09:12

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:09:07', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered 'No (N)'	System	10 Aug 2020 03:09:12

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-09T22:09:10', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '96e4aa9b-483e-497d-8156-db0378b30692'	System	10 Aug 2020 03:09:12
User entered '09 Aug 2020 22:09'	System	10 Aug 2020 03:09:12

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 6'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:22', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'None (0)'	System	11 Aug 2020 03:42:57



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:30', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'None (0)'	System	11 Aug 2020 03:42:57

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:34', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'None (0)'	System	11 Aug 2020 03:42:57

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'None (0)'	System	11 Aug 2020 03:42:57

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:42', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'None (0)'	System	11 Aug 2020 03:42:57

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:45', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'None (0)'	System	11 Aug 2020 03:42:57

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:52', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered 'No (N)'	System	11 Aug 2020 03:42:57

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-10T22:42:55', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e5bacad6-59fd-4c40-9acc-1add1032b20b'	System	11 Aug 2020 03:42:57
User entered '10 Aug 2020 22:42'	System	11 Aug 2020 03:42:57

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 18:46:53



**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 7'	System	05 Aug 2020 18:46:53

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:52', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'None (0)'	System	12 Aug 2020 14:10:20

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:55', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'None (0)'	System	12 Aug 2020 14:10:20

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:09:58', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'None (0)'	System	12 Aug 2020 14:10:20

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:10:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'None (0)'	System	12 Aug 2020 14:10:20

US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:10:05', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'None (0)'	System	12 Aug 2020 14:10:20

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:10:08', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'None (0)'	System	12 Aug 2020 14:10:20



US3092022

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:10:13', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered 'No (N)'	System	12 Aug 2020 14:10:20

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-08-12T09:10:16', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '5c3d38c8-286d-4a88-b1de-b237293ce27c'	System	12 Aug 2020 14:10:20
User entered '12 Aug 2020 09:10'	System	12 Aug 2020 14:10:20

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 18:46:53

US3092022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:52:41
User closed query 'File Safety Call documentation in source.' (Site from CRA).		12 Nov 2020 17:52:39
Query 'File Safety Call documentation in source.' answered with 'will add ' (Site from CRA).	destiny robinson (b) (4)	29 Oct 2020 00:42:22
User opened query 'File Safety Call documentation in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:22:26
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	15 Aug 2020 18:30:22

**US3092022**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:52:42
User entered '15 Aug 2020'	Catina Adams (b) (4) (b) (4)	15 Aug 2020 18:30:22

US3092022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:52:43
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4) (b) (4)	15 Aug 2020 18:30:22

US3092022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:52:45
User entered empty.	Catina Adams (b) (4) (b) (4)	15 Aug 2020 18:30:22



US3092022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:52:49
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	15 Aug 2020 18:31:26

**US3092022**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'I'	System	15 Aug 2020 18:31:26

US3092022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:03
User closed query 'File Safety Call Day 15 documentation in source.' (Site from CRA).		12 Nov 2020 17:53:01
Query 'File Safety Call Day 15 documentation in source.' answered with 'will add ' (Site from CRA).	destiny robinson (b) (4)	29 Oct 2020 00:42:10
User opened query 'File Safety Call Day 15 documentation in source.' (Site from CRA).	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:23:00
	Catina Adams (b) (4)	09 Sep 2020 11:12:45
	(b) (4)	

**US3092022**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:04
User entered '19 Aug 2020'	Catina Adams (b) (4) (b) (4)	09 Sep 2020 11:12:45

**US3092022**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:06
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4) (b) (4)	09 Sep 2020 11:12:45

US3092022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:07
User entered empty.	Catina Adams (b) (4) (b) (4)	09 Sep 2020 11:12:45

US3092022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:20
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:35:47

**US3092022**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:34:08
User entered 'I'	System	02 Sep 2020 17:35:47



US3092022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:03:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:31
User closed query 'File Safety Call Day 22 documentation in source.' (Site from CRA).		12 Nov 2020 17:53:27
Query 'File Safety Call Day 22 documentation in source.' answered with 'will add ' (Site from CRA).	destiny robinson (b) (4)	29 Oct 2020 00:43:30
User opened query 'File Safety Call Day 22 documentation in source.' (Site from CRA).	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 16:24:37
	Catina Adams (b) (4)	09 Sep 2020 11:14:32
	(b) (4)	

**US3092022**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:03:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:32
User entered '27 Aug 2020'	Catina Adams (b) (4) (b) (4)	09 Sep 2020 11:14:32

US3092022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:03:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:34
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4) (b) (4)	09 Sep 2020 11:14:32

US3092022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:03:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:36
User entered empty.	Catina Adams (b) (4) (b) (4)	09 Sep 2020 11:14:32

**US3092022**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:03:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:48
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:41

**US3092022**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:03:09
User entered 'I'	System	02 Sep 2020 17:36:41

US3092022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:22:45
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:37:12

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:22:45
User entered '2 Sep 2020'	Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:37:12



US3092022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:00

[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 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:22:45
User entered 'Clinic (Clinic)'	Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:37:12

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'VISIT2'	System	02 Sep 2020 17:37:12

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User accepted default value 'Pre-Dose (PREDOSE)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered '2 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered '12:00'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '2 Sep 2020 12:00'	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Sep 2020 21:09:19
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	22 Sep 2020 21:09:19
User entered '98.2' F reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 21:09:19
Amendment Manager: User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:44:22
User entered '98.2' C	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50



US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered 'Oral (Oral)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Sep 2020 17:41:16
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'bradycardia abnormal ncs with no AE per PI ' (Site from System).	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:05:31
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 17:51:50
User entered '41'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'bpm'	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered '18'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'breaths/min'	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered '135'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'mmHg'	System	02 Sep 2020 17:51:50



US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered '82'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'mmHg'	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User accepted default value 'Post-Dose (POSTDOSE)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered '2 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:03:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 18:03:17
User entered '12:59' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:03:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:51:50
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '2 Sep 2020 12:59'	System	02 Sep 2020 18:03:17
User entered empty.	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:03:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 18:03:17
User entered '97.0' F reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:03:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:51:50
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50



US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	02 Sep 2020 18:03:17
User entered empty.	(b) (4) Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:04:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:03:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 18:03:17
User entered '52' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:03:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:51:50
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'bpm'	System	02 Sep 2020 18:03:17
User entered empty.	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:03:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 18:03:17
User entered '16' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:03:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:51:50
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'breaths/min'	System	02 Sep 2020 18:03:17
User entered empty.	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Sep 2020 17:41:04
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'abnormal ncs, no ae per PI' (Site from System).	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:43:35
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 18:03:17
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:03:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 18:03:17
User entered '157' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:03:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:51:50
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'mmHg'	System	02 Sep 2020 18:03:17
User entered empty.	System	02 Sep 2020 17:51:50



US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:37
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 18:03:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		02 Sep 2020 18:03:17
User entered '97' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 18:03:17
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 17:51:50
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'mmHg'	System	02 Sep 2020 18:03:17
User entered empty.	System	02 Sep 2020 17:51:50

US3092022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:53
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:57

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:04:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:23:53
User entered '02 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:51:57

US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:59

US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:59

US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

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)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:59

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:00**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 17:36:59



US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '2 Sep 2020'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:59

US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '12:25'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:59

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:00**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '2 Sep 2020 12:25'	System	02 Sep 2020 17:36:59

US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:36:59

US3092022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:04:00

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:43:40
User entered 'ONCE'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:04:00**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 17:36:59

US3092022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:25
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:55:36

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:25
User entered '02 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:55:36



**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:25
User entered '12:21'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:55:36

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '02 Sep 2020 12:21'	System	02 Sep 2020 17:55:36

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:51
User entered '02 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33

US3092022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:04:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:51
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33

US3092022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:04:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:20:21
User closed query 'Per source, collection is 12:18, please review and correct.' (Site from CRA).		13 Nov 2020 18:20:19
User entered '12:18' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	27 Oct 2020 21:03:12
Query 'Per source, collection is 12:18, please review and correct.' answered with 'confirmed' (Site from CRA).	destiny robinson (b) (4) (b) (4)	27 Oct 2020 21:02:58
User opened query 'Per source, collection is 12:18, please review and correct.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 19:25:30
DataPoint Un-verified.		14 Oct 2020 19:24:56
DataPoint Verified.		14 Oct 2020 19:24:51
User entered '12:21'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '02 Sep 2020 12:18'	System	27 Oct 2020 21:03:12
User entered '02 Sep 2020 12:21'	System	02 Sep 2020 17:56:33

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33



**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:51
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:24:51
User entered empty.	Vicki Martinez (b) (4) (b) (4)	02 Sep 2020 17:56:33

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered empty.	System	02 Sep 2020 17:56:33

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:25:34
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	02 Sep 2020 17:37:19

**US3092022**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'I'	System	02 Sep 2020 17:37:19

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:57:53', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'fec768ff-5c63-47b4-98a7-cc8d761a4df2'	System	02 Sep 2020 17:59:05
User entered 'Yes (Y)'	System	02 Sep 2020 17:59:05

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:58:51', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'fec768ff-5c63-47b4-98a7-cc8d761a4df2'	System	02 Sep 2020 17:59:05
User entered '97.0'	System	02 Sep 2020 17:59:05



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:58:56', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'fec768ff-5c63-47b4-98a7-cc8d761a4df2'	System	02 Sep 2020 17:59:05
User entered 'No (N)'	System	02 Sep 2020 17:59:05

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'fec768ff-5c63-47b4-98a7-cc8d761a4df2'	System	02 Sep 2020 17:59:05
User entered '02 Sep 2020 12:59'	System	02 Sep 2020 17:59:05

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 12:45'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 15:15'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:38', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd9c97545-d003-4b17-a0b7-6c6be2d3a0a0'	System	03 Sep 2020 15:12:57
User entered 'Yes (Y)'	System	03 Sep 2020 15:12:57

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:46', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd9c97545-d003-4b17-a0b7-6c6be2d3a0a0'	System	03 Sep 2020 15:12:57
User entered '98.0'	System	03 Sep 2020 15:12:57

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:50', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd9c97545-d003-4b17-a0b7-6c6be2d3a0a0'	System	03 Sep 2020 15:12:57
User entered 'No (N)'	System	03 Sep 2020 15:12:57



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:53', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd9c97545-d003-4b17-a0b7-6c6be2d3a0a0'	System	03 Sep 2020 15:12:57
User entered '03 Sep 2020 10:12'	System	03 Sep 2020 15:12:57

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 16:10'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 2'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:28:47', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3dc79087-86e2-44bd-9e89-3024c49b9e25'	System	04 Sep 2020 15:29:05
User entered 'Yes (Y)'	System	04 Sep 2020 15:29:05

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:28:54', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3dc79087-86e2-44bd-9e89-3024c49b9e25'	System	04 Sep 2020 15:29:05
User entered '99.6'	System	04 Sep 2020 15:29:05

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:28:58', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3dc79087-86e2-44bd-9e89-3024c49b9e25'	System	04 Sep 2020 15:29:05
User entered 'No (N)'	System	04 Sep 2020 15:29:05

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3dc79087-86e2-44bd-9e89-3024c49b9e25'	System	04 Sep 2020 15:29:05
User entered '04 Sep 2020 10:29'	System	04 Sep 2020 15:29:05



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 3'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 4'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 5'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:03:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '43bd72cd-0603-43b2-82c4-0ea958f3e539'	System	06 Sep 2020 17:05:39
User entered 'Yes (Y)'	System	06 Sep 2020 17:05:39

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:05:31', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '43bd72cd-0603-43b2-82c4-0ea958f3e539'	System	06 Sep 2020 17:05:39
User entered '98.0'	System	06 Sep 2020 17:05:39

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:05:35', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '43bd72cd-0603-43b2-82c4-0ea958f3e539'	System	06 Sep 2020 17:05:39
User entered 'No (N)'	System	06 Sep 2020 17:05:39



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:05:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '43bd72cd-0603-43b2-82c4-0ea958f3e539'	System	06 Sep 2020 17:05:39
User entered '06 Sep 2020 12:05'	System	06 Sep 2020 17:05:39

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 6'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 7'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:06', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b3c6b9f-f10f-4094-9f62-3cb84bcd74ed'	System	02 Sep 2020 17:59:33
User entered 'None (1)'	System	02 Sep 2020 17:59:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:10', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b3c6b9f-f10f-4094-9f62-3cb84bcd74ed'	System	02 Sep 2020 17:59:33
User entered 'No (N)'	System	02 Sep 2020 17:59:33



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:21', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b3c6b9f-f10f-4094-9f62-3cb84bcd74ed'	System	02 Sep 2020 17:59:33
User entered 'No (N)'	System	02 Sep 2020 17:59:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:26', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b3c6b9f-f10f-4094-9f62-3cb84bcd74ed'	System	02 Sep 2020 17:59:33
User entered 'None (1)'	System	02 Sep 2020 17:59:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:28', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b3c6b9f-f10f-4094-9f62-3cb84bcd74ed'	System	02 Sep 2020 17:59:33
User entered '02 Sep 2020 12:59'	System	02 Sep 2020 17:59:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 12:45'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 15:15'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:11:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 15:12:31

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:11:25', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered 'Yes (Y)'	System	03 Sep 2020 15:12:31



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:11:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered '6'	System	03 Sep 2020 15:12:31

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:08', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered 'Yes (Y)'	System	03 Sep 2020 15:12:31

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:18', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered '5'	System	03 Sep 2020 15:12:31

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:22', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered 'None (1)'	System	03 Sep 2020 15:12:31

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:25', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8dbf108d-f392-4419-8202-a8c6ac01f4f9'	System	03 Sep 2020 15:12:31
User entered '03 Sep 2020 10:12'	System	03 Sep 2020 15:12:31

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 16:10'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 2'	System	02 Sep 2020 17:36:59



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:12', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e46e9026-8173-4cca-8c9f-4bbc90c1f0c5'	System	04 Sep 2020 15:29:32
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 15:29:32

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:20', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e46e9026-8173-4cca-8c9f-4bbc90c1f0c5'	System	04 Sep 2020 15:29:32
User entered 'No (N)'	System	04 Sep 2020 15:29:32

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:23', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e46e9026-8173-4cca-8c9f-4bbc90c1f0c5'	System	04 Sep 2020 15:29:32
User entered 'No (N)'	System	04 Sep 2020 15:29:32

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:27', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e46e9026-8173-4cca-8c9f-4bbc90c1f0c5'	System	04 Sep 2020 15:29:32
User entered 'None (1)'	System	04 Sep 2020 15:29:32

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:29', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e46e9026-8173-4cca-8c9f-4bbc90c1f0c5'	System	04 Sep 2020 15:29:32
User entered '04 Sep 2020 10:29'	System	04 Sep 2020 15:29:32

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 3'	System	02 Sep 2020 17:36:59



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:04:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:36:59



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 4'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 5'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:08', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4784e796-1714-43d5-a154-d2a945bb6eba'	System	06 Sep 2020 17:02:49
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 17:02:49

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:12', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4784e796-1714-43d5-a154-d2a945bb6eba'	System	06 Sep 2020 17:02:49
User entered 'No (N)'	System	06 Sep 2020 17:02:49

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:15', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4784e796-1714-43d5-a154-d2a945bb6eba'	System	06 Sep 2020 17:02:49
User entered 'No (N)'	System	06 Sep 2020 17:02:49

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4784e796-1714-43d5-a154-d2a945bb6eba'	System	06 Sep 2020 17:02:49
User entered 'None (1)'	System	06 Sep 2020 17:02:49



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:21', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4784e796-1714-43d5-a154-d2a945bb6eba'	System	06 Sep 2020 17:02:49
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:02:49

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 6'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 7'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:04:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 17:36:59



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:34', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'None (0)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'None (0)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:40', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'None (0)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:43', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'None (0)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:46', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'None (0)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:48', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'None (0)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:53', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered 'No (N)'	System	02 Sep 2020 17:59:57

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-02T12:59:55', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'ff53d5e0-50bf-400a-bf9b-1ae47ef2cdca'	System	02 Sep 2020 17:59:57
User entered '02 Sep 2020 12:59'	System	02 Sep 2020 17:59:57



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 12:45'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 15:15'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:12:58', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'None (0)'	System	03 Sep 2020 15:13:20

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'None (0)'	System	03 Sep 2020 15:13:20

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:03', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'None (0)'	System	03 Sep 2020 15:13:20

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:06', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'None (0)'	System	03 Sep 2020 15:13:20

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:09', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'None (0)'	System	03 Sep 2020 15:13:20



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:11', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'None (0)'	System	03 Sep 2020 15:13:20

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:15', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered 'No (N)'	System	03 Sep 2020 15:13:20

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-03T10:13:17', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '097c9fa5-f972-4af6-9e7e-ee2da87ec001'	System	03 Sep 2020 15:13:20
User entered '03 Sep 2020 10:13'	System	03 Sep 2020 15:13:20

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '02 Sep 2020 16:10'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 2'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:34', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'None (0)'	System	04 Sep 2020 15:29:53

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:36', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'None (0)'	System	04 Sep 2020 15:29:53



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:38', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'None (0)'	System	04 Sep 2020 15:29:53

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:40', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'None (0)'	System	04 Sep 2020 15:29:53

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:43', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'None (0)'	System	04 Sep 2020 15:29:53

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:45', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'None (0)'	System	04 Sep 2020 15:29:53

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:47', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered 'No (N)'	System	04 Sep 2020 15:29:53

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-04T10:29:49', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '9e0b96d1-2f5d-4ed8-8514-662dc3b4621c'	System	04 Sep 2020 15:29:53
User entered '04 Sep 2020 10:29'	System	04 Sep 2020 15:29:53

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 17:36:59



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 3'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 4'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 5'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:29', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'None (0)'	System	06 Sep 2020 17:03:18



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:31', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'None (0)'	System	06 Sep 2020 17:03:18

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:33', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'None (0)'	System	06 Sep 2020 17:03:18

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:37', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'None (0)'	System	06 Sep 2020 17:03:18

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:39', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'None (0)'	System	06 Sep 2020 17:03:18

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:41', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'None (0)'	System	06 Sep 2020 17:03:18

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:45', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered 'No (N)'	System	06 Sep 2020 17:03:18

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-09-06T12:02:56', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8433804b-0a9b-4d85-a325-de876d44a444'	System	06 Sep 2020 17:03:18
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:03:18

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 17:36:59



**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 6'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	02 Sep 2020 17:36:59
User entered 'Day 7'	System	02 Sep 2020 17:36:59

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33



US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

US3092022

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:04:00

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:04:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 17:36:59

**US3092022**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:25
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:02



**US3092022**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:25
User entered empty.	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:02

**US3092022**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:25
User entered empty.	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:02

US3092022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:55:25
User entered empty.	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:02

US3092022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:14:27
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 11:43:33

**US3092022**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'I'	System	07 Oct 2020 11:43:33

US3092022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:20:50
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 00:42:58
User entered 'No (N)' reason for change: Data Entry Error	System	29 Oct 2020 00:42:58
User opened query 'Data is required. Please complete.' (Site from System).	destiny robinson (b) (4)	29 Oct 2020 00:42:58
User entered empty.	(b) (4)	
	System	28 Oct 2020 19:54:18
	destiny robinson (b) (4)	28 Oct 2020 19:54:18
	(b) (4)	

**US3092022**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:20:50
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	28 Oct 2020 19:54:18

**US3092022**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:20:50
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	28 Oct 2020 19:54:18



**US3092022**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:20:50
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	28 Oct 2020 19:54:18

**US3092022**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:20:56
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 11:43:43

**US3092022**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'I'	System	07 Oct 2020 11:43:43

**US3092022**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:21:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:08

**US3092022**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:21:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:08

**US3092022**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:21:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:08

**US3092022**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:21:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:43:08

**US3092022**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:21:05
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 11:43:55



**US3092022**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'I'	System	07 Oct 2020 11:43:55

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:29:57
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:18:34

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:29:57
User entered '7 Oct 2020'	Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:18:34

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[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 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:29:57
User entered 'Clinic (Clinic)'	Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:18:34

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'VISIT3'	System	07 Oct 2020 16:18:34

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '7 Oct 2020'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '10:40'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19



**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '7 Oct 2020 10:40'	System	07 Oct 2020 16:58:19

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '98.4' F	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '55'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'bpm'	System	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '16'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'breaths/min'	System	07 Oct 2020 16:58:19



US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Per CDM: Systolic blood pressure is out of range. Please indicate if CS or NCS and report as AE,If appropriate	(b) (4) (b) (4), (b) (6)	30 Oct 2020 13:32:12
' (Site from DM). Query 'Per CDM: Systolic blood pressure is out of range. Please indicate if CS or NCS and report as AE,If appropriate	destiny robinson (b) (4) (b) (4)	27 Oct 2020 21:05:45
' answered with 'abnormal ncvs ' (Site from DM). User opened query 'Per CDM: Systolic blood pressure is out of range. Please indicate if CS or NCS and report as AE,If appropriate	(b) (4), (b) (6)	21 Oct 2020 09:06:57
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '167'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'mmHg'	System	07 Oct 2020 16:58:19

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:30:31
User entered '79'	Marissa Cervenka (b) (4) (b) (4)	07 Oct 2020 16:58:19

US3092022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'mmHg'	System	07 Oct 2020 16:58:19

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32

US3092022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:25:55
User closed query 'Physical Exam not filed in subject source. ' (Site from CRA).		30 Mar 2021 16:25:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
Query 'Physical Exam not filed in subject source. ' answered with 'will add to chart ' (Site from CRA).	(b) (4)	
User opened query 'Physical Exam not filed in subject source. ' (Site from CRA).	destiny robinson (b) (4)	19 Oct 2020 20:03:30
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:32:02
		14 Oct 2020 19:31:27
DataPoint Verified.		14 Oct 2020 19:31:24
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Oct 2020 16:19:26
	(b) (4)	

US3092022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:25:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:31:29
DataPoint Verified.		14 Oct 2020 19:31:24
User entered '7 Oct 2020'	Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:19:26



US3092022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:27:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:19:52

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:27:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '7 Oct 2020'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:19:52

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:27:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '11:07'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:19:52

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered '7 Oct 2020 11:07'	System	07 Oct 2020 16:19:52

US3092022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 16:25:00
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	07 Oct 2020 16:19:59

**US3092022**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'I'	System	07 Oct 2020 16:19:59

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 64'	System	05 Aug 2020 18:46:53

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 71'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 78'	System	05 Aug 2020 18:46:53

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

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**Generated On: 09 Jun 2021 15:04:00**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

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**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
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**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 92'	System	05 Aug 2020 18:46:53

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-11-05T15:11:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '18d09ea8-5d5f-4434-9810-2100ba35e016'	System	05 Nov 2020 21:12:10
User entered 'No (N)'	System	05 Nov 2020 21:12:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-11-05T15:12:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '18d09ea8-5d5f-4434-9810-2100ba35e016'	System	05 Nov 2020 21:12:10
User entered 'No (N)'	System	05 Nov 2020 21:12:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-11-05T15:12:05', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '18d09ea8-5d5f-4434-9810-2100ba35e016'	System	05 Nov 2020 21:12:10
User entered '05 Nov 2020 15:12:05'	System	05 Nov 2020 21:12:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 18:46:53



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 99'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: Safety Follow Up Diary (1)**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

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**Folder: Safety Follow Up Diary (1)**

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:39:10
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered 'Day 106'	System	05 Aug 2020 18:46:53

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-11-16T14:07:47', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '7a05c489-dce8-4994-b6a4-8ca1bfd81128'	System	16 Nov 2020 20:08:02
User entered 'No (N)'	System	16 Nov 2020 20:08:02

US3092022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-11-16T14:07:54', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '7a05c489-dce8-4994-b6a4-8ca1bfd81128'	System	16 Nov 2020 20:08:02
User entered 'No (N)'	System	16 Nov 2020 20:08:02

**US3092022**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-11-16T14:07:58', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '7a05c489-dce8-4994-b6a4-8ca1bfd81128'	System	16 Nov 2020 20:08:02
User entered '16 Nov 2020 14:07:58'	System	16 Nov 2020 20:08:02



**US3092022**

**Folder: Safety Follow Up Diary (1)**

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:03:33
Data entry locked.	System	05 Aug 2020 18:46:53
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 18:46:53

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2020-12-01T10:39:33', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bf307e8-d0cb-4843-a04e-8e5bee1c1fab'	System	01 Dec 2020 16:39:49
User entered 'No (N)'	System	01 Dec 2020 16:39:49

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2020-12-01T10:39:39', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bf307e8-d0cb-4843-a04e-8e5bee1c1fab'	System	01 Dec 2020 16:39:49
User entered 'No (N)'	System	01 Dec 2020 16:39:49



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-12-01T10:39:42', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '3bf307e8-d0cb-4843-a04e-8e5bee1c1fab'	System	01 Dec 2020 16:39:49
User entered '01 Dec 2020 10:39:42'	System	01 Dec 2020 16:39:49

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2020-12-04T12:51:51', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'c59399d3-66f5-42be-b409-4e9704b4eea4'	System	04 Dec 2020 18:52:02
User entered 'No (N)'	System	04 Dec 2020 18:52:02

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2020-12-04T12:51:56', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'c59399d3-66f5-42be-b409-4e9704b4eea4'	System	04 Dec 2020 18:52:02
User entered 'No (N)'	System	04 Dec 2020 18:52:02

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-12-04T12:52:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'c59399d3-66f5-42be-b409-4e9704b4eea4'	System	04 Dec 2020 18:52:02
User entered '04 Dec 2020 12:52:00'	System	04 Dec 2020 18:52:02

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2020-12-15T13:12:04', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2de2bf2b-e663-474f-b951-6b2b9578c996'	System	15 Dec 2020 19:12:20
User entered 'No (N)'	System	15 Dec 2020 19:12:20

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2020-12-15T13:12:09', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2de2bf2b-e663-474f-b951-6b2b9578c996'	System	15 Dec 2020 19:12:20
User entered 'No (N)'	System	15 Dec 2020 19:12:20

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-12-15T13:12:15', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2de2bf2b-e663-474f-b951-6b2b9578c996'	System	15 Dec 2020 19:12:20
User entered '15 Dec 2020 13:12:15'	System	15 Dec 2020 19:12:20

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2020-12-29T15:29:41', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '83b52677-4049-4036-ada5-3db3cda167b3'	System	29 Dec 2020 21:29:57
User entered 'No (N)'	System	29 Dec 2020 21:29:57

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2020-12-29T15:29:46', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '83b52677-4049-4036-ada5-3db3cda167b3'	System	29 Dec 2020 21:29:57
User entered 'No (N)'	System	29 Dec 2020 21:29:57

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2020-12-29T15:29:50', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '83b52677-4049-4036-ada5-3db3cda167b3'	System	29 Dec 2020 21:29:57
User entered '29 Dec 2020 15:29:50'	System	29 Dec 2020 21:29:57

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-01-05T12:21:31', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8707c411-ad8c-49a8-96f2-4e38344a03de'	System	05 Jan 2021 18:21:43
User entered 'No (N)'	System	05 Jan 2021 18:21:43

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-01-05T12:21:35', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8707c411-ad8c-49a8-96f2-4e38344a03de'	System	05 Jan 2021 18:21:43
User entered 'No (N)'	System	05 Jan 2021 18:21:43

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-01-05T12:21:38', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8707c411-ad8c-49a8-96f2-4e38344a03de'	System	05 Jan 2021 18:21:43
User entered '05 Jan 2021 12:21:38'	System	05 Jan 2021 18:21:43

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-01-11T11:21:52', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '0c7003d3-56d0-41c0-997f-9bc714d55f59'	System	11 Jan 2021 17:22:08
User entered 'No (N)'	System	11 Jan 2021 17:22:08



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-01-11T11:21:58', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '0c7003d3-56d0-41c0-997f-9bc714d55f59'	System	11 Jan 2021 17:22:08
User entered 'No (N)'	System	11 Jan 2021 17:22:08

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-01-11T11:22:02', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '0c7003d3-56d0-41c0-997f-9bc714d55f59'	System	11 Jan 2021 17:22:08
User entered '11 Jan 2021 11:22:02'	System	11 Jan 2021 17:22:08

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-01-19T11:29:15', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2c5279d9-0e9b-46d2-860c-6e82b259cf15'	System	19 Jan 2021 17:29:27
User entered 'No (N)'	System	19 Jan 2021 17:29:27

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-01-19T11:29:19', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2c5279d9-0e9b-46d2-860c-6e82b259cf15'	System	19 Jan 2021 17:29:27
User entered 'No (N)'	System	19 Jan 2021 17:29:27

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-01-19T11:29:23', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '2c5279d9-0e9b-46d2-860c-6e82b259cf15' User entered '19 Jan 2021 11:29:23'	System	19 Jan 2021 17:29:27



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-01-29T12:29:57', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'bb3ec691-9696-49bf-aaef-f41515a915b4'	System	29 Jan 2021 18:30:08
User entered 'No (N)'	System	29 Jan 2021 18:30:08

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-01-29T12:30:01', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'bb3ec691-9696-49bf-aaef-f41515a915b4'	System	29 Jan 2021 18:30:08
User entered 'No (N)'	System	29 Jan 2021 18:30:08



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-01-29T12:30:04', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'bb3ec691-9696-49bf-aaef-f41515a915b4'	System	29 Jan 2021 18:30:08
User entered '29 Jan 2021 12:30:04'	System	29 Jan 2021 18:30:08

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-02-13T12:59:21', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '33632ab7-480c-4b89-9e2a-be3e24009ab1'	System	13 Feb 2021 18:59:35
User entered 'No (N)'	System	13 Feb 2021 18:59:35



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-02-13T12:59:26', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '33632ab7-480c-4b89-9e2a-be3e24009ab1'	System	13 Feb 2021 18:59:35
User entered 'No (N)'	System	13 Feb 2021 18:59:35

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-02-13T12:59:30', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '33632ab7-480c-4b89-9e2a-be3e24009ab1' User entered '13 Feb 2021 12:59:30'	System	13 Feb 2021 18:59:35

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-02-20T13:22:16', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b6a7ed4-dd4b-4b85-b851-00d396c302ac'	System	20 Feb 2021 19:22:37
User entered 'No (N)'	System	20 Feb 2021 19:22:37

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-02-20T13:22:29', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b6a7ed4-dd4b-4b85-b851-00d396c302ac'	System	20 Feb 2021 19:22:37
User entered 'No (N)'	System	20 Feb 2021 19:22:37

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bcaa2b94bda2)', Time: '2021-02-20T13:22:33', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '8b6a7ed4-dd4b-4b85-b851-00d396c302ac'	System	20 Feb 2021 19:22:37
User entered '20 Feb 2021 13:22:33'	System	20 Feb 2021 19:22:37



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-02-26T09:42:53', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '1b2b20d0-51de-4b1b-b70e-93b1f19d1d18'	System	26 Feb 2021 15:43:12
User entered 'No (N)'	System	26 Feb 2021 15:43:12

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-02-26T09:43:04', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '1b2b20d0-51de-4b1b-b70e-93b1f19d1d18'	System	26 Feb 2021 15:43:12
User entered 'No (N)'	System	26 Feb 2021 15:43:12

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-02-26T09:43:08', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '1b2b20d0-51de-4b1b-b70e-93b1f19d1d18'	System	26 Feb 2021 15:43:12
User entered '26 Feb 2021 09:43:08'	System	26 Feb 2021 15:43:12

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-03-13T20:04:54-06:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e67bb47e-295b-4978-a5d8-4369fad163df' User entered 'No (N)'	System	14 Mar 2021 02:09:38
	System	14 Mar 2021 02:09:38

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-03-13T20:04:59-06:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e67bb47e-295b-4978-a5d8-4369fad163df' User entered 'No (N)'	System	14 Mar 2021 02:09:38

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-03-13T20:05:02-06:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'e67bb47e-295b-4978-a5d8-4369fad163df'	System	14 Mar 2021 02:09:38
User entered '13 Mar 2021 20:05:02'	System	14 Mar 2021 02:09:38

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-03-23T10:58:21-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '378b72f1-e1f4-4218-8741-d909e82fed1e' User entered 'No (N)'	System	23 Mar 2021 15:58:37
	System	23 Mar 2021 15:58:37

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-03-23T10:58:26-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '378b72f1-e1f4-4218-8741-d909e82fed1e'	System	23 Mar 2021 15:58:37
User entered 'No (N)'	System	23 Mar 2021 15:58:37

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-03-23T10:58:29-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '378b72f1-e1f4-4218-8741-d909e82fed1e' User entered '23 Mar 2021 10:58:29'	System	23 Mar 2021 15:58:37
	System	23 Mar 2021 15:58:37

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-03-29T12:57:28-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6bbc1c22-3f47-4668-a2a9-76ab46d8c681'	System	29 Mar 2021 17:57:42
User entered 'No (N)'	System	29 Mar 2021 17:57:42

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-03-29T12:57:33-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6bbc1c22-3f47-4668-a2a9-76ab46d8c681'	System	29 Mar 2021 17:57:42
User entered 'No (N)'	System	29 Mar 2021 17:57:42

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-03-29T12:57:36-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '6bbc1c22-3f47-4668-a2a9-76ab46d8c681' User entered '29 Mar 2021 12:57:36'	System	29 Mar 2021 17:57:42
	System	29 Mar 2021 17:57:42

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-04-02T23:05:16-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'f8135bfe-7584-4ea0-a261-8bcfabe8f009'	System	03 Apr 2021 04:05:31
User entered 'No (N)'	System	03 Apr 2021 04:05:31

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-04-02T23:05:22-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'f8135bfe-7584-4ea0-a261-8bcfabe8f009'	System	03 Apr 2021 04:05:31
User entered 'No (N)'	System	03 Apr 2021 04:05:31



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-04-02T23:05:27-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'f8135bfe-7584-4ea0-a261-8bcfabe8f009'	System	03 Apr 2021 04:05:31
User entered '02 Apr 2021 23:05:27'	System	03 Apr 2021 04:05:31

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-04-11T00:58:22-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4926cf3f-19e8-41d1-90e5-d4517fc96386'	System	11 Apr 2021 05:58:36
User entered 'No (N)'	System	11 Apr 2021 05:58:36

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-04-11T00:58:29-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4926cf3f-19e8-41d1-90e5-d4517fc96386'	System	11 Apr 2021 05:58:36
User entered 'No (N)'	System	11 Apr 2021 05:58:36

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-04-11T00:58:32-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '4926cf3f-19e8-41d1-90e5-d4517fc96386'	System	11 Apr 2021 05:58:36
User entered '11 Apr 2021 00:58:32'	System	11 Apr 2021 05:58:36

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (c89bccaa2b94bda2)', Time: '2021-04-19T01:02:26-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '624bcb60-f97c-4e5e-add9-18575a6d986a' User entered 'No (N)'	System	19 Apr 2021 06:02:58
	System	19 Apr 2021 06:02:58

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (c89bccaa2b94bda2)', Time: '2021-04-19T01:02:35-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '624bcb60-f97c-4e5e-add9-18575a6d986a' User entered 'No (N)'	System	19 Apr 2021 06:02:58

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-04-19T01:02:38-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '624bcb60-f97c-4e5e-add9-18575a6d986a' User entered '19 Apr 2021 01:02:38'	System	19 Apr 2021 06:02:58
	System	19 Apr 2021 06:02:58

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (E804D9ED-FB0D-4F49-A40A-C74C74CBB349)', Time: '2021-04-26T12:31:30-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'c6fdde4e-a4ca-41c0-a5d8-120c4ff1694e' User entered 'No (N)'	System	26 Apr 2021 17:31:42

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (E804D9ED-FB0D-4F49-A40A-C74C74CBB349)', Time: '2021-04-26T12:31:36-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'c6fdde4e-a4ca-41c0-a5d8-120c4ff1694e' User entered 'No (N)'	System	26 Apr 2021 17:31:42

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E804D9ED-FB0D-4F49-A40A-C74C74CBB349)', Time: '2021-04-26T12:31:39-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'c6fdde4e-a4ca-41c0-a5d8-120c4ff1694e' User entered '26 Apr 2021 12:31:39'	System	26 Apr 2021 17:31:42
	System	26 Apr 2021 17:31:42

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[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 (E804D9ED-FB0D-4F49-A40A-C74C74CBB349)', Time: '2021-04-30T19:13:21-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '756085c5-8c9f-45fb-987d-c98c0b98a869'	System	01 May 2021 00:13:46
User entered 'No (N)'	System	01 May 2021 00:13:46

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

Have you been exposed to someone with 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 (E804D9ED-FB0D-4F49-A40A-C74C74CBB349)', Time: '2021-04-30T19:13:39-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '756085c5-8c9f-45fb-987d-c98c0b98a869'	System	01 May 2021 00:13:46
User entered 'No (N)'	System	01 May 2021 00:13:46



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E804D9ED-FB0D-4F49-A40A-C74C74CBB349)', Time: '2021-04-30T19:13:42-05:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: '756085c5-8c9f-45fb-987d-c98c0b98a869' User entered '30 Apr 2021 19:13:42'	System	01 May 2021 00:13:46
	System	01 May 2021 00:13:46

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:39:10



**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:39:10

**US3092022**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:04:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:39:10
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:39:10

US3092022

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:04:00

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-03-02T10:43:03-06:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd426eb65-d10a-48b4-ba31-0b30ca6e34af' User entered 'No (N)'	System	02 Mar 2021 16:43:12
	System	02 Mar 2021 16:43:12

**US3092022**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:39:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c89bccaa2b94bda2)', Time: '2021-03-02T10:43:08-06:00', User OID: 'PatientReportedOutcome (US3092022)', ODM File OID: 'd426eb65-d10a-48b4-ba31-0b30ca6e34af'	System	02 Mar 2021 16:43:12
User entered '02 Mar 2021 10:43:08'	System	02 Mar 2021 16:43:12

**US3092022**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 18:17:25
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 17:01:20

US3092022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 18:17:28
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 06:23:06
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Visit out of window.' (Site from System).	Catina Adams (b) (4) (b) (4)	01 Dec 2020 17:08:18
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Dec 2020 17:01:20
User entered '5 Nov 2020'	Catina Adams (b) (4) (b) (4)	01 Dec 2020 17:01:20



**US3092022**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 18:17:30
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 17:01:20

US3092022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 18:17:33
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 17:01:20

**US3092022**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
DataPoint Verified.		30 Mar 2021 18:17:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 16:57:44

**US3092022**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:32
User entered 'I'	System	01 Dec 2020 16:57:44

**US3092022**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:24:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 16:58:04

**US3092022**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:24:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '1 Dec 2020'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 16:58:04

**US3092022**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:24:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 16:58:04

**US3092022**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:24:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 16:58:04



**US3092022**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:24:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) Catina Adams (b) (4) (b) (4)	01 Dec 2020 16:58:20

**US3092022**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
User entered 'I'	System	01 Dec 2020 16:58:20

**US3092022**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:29:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:47:15

US3092022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:29:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 06:12:05
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with '1st attempt was in window. Date of contact correct.' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 15:48:37
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	05 Jan 2021 15:47:15
User entered '04 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 15:47:15

**US3092022**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:29:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:24:36
User entered 'Contact Made (CONTACT MADE)'		05 Jan 2021 15:47:15

US3092022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:29:21
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '1ST ATTEMPT ON 12/28/20 2ND ATTEMPT ON 12/30/20 3rd attempt on 01/04/21' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:24:36
User entered '1st attempt on 12/28/20 2nd attempt on 12/30/20' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 15:49:02
User entered empty.		05 Jan 2021 15:47:15

**US3092022**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:29:27
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:49:07

**US3092022**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
User entered 'I'	System	05 Jan 2021 15:49:07



**US3092022**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:30:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:26:35

**US3092022**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:30:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:26:35

**US3092022**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:30:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:26:35

**US3092022**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:30:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:26:35

**US3092022**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
DataPoint Verified.		30 Mar 2021 18:30:13
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:31:08

**US3092022**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:14:49
User entered 'I'	System	01 Feb 2021 21:31:08

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:11
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:50:41

US3092022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:04:00

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:11
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		05 Apr 2021 19:07:44
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'CONFIRMED, DATA CORRECT' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:35
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Apr 2021 22:50:41
User entered '01 Apr 2021'	(b) (4), (b) (6)	01 Apr 2021 22:50:41



**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:11
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:50:41

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 22:50:41

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '14:12'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 14:12'	System	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58



**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '64'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '18'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 22:51:58

US3092022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '104'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 22:51:58

US3092022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:04:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:22
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '64'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:51:58



**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:04:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 22:51:58

US3092022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:04:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:26
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:52:07

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:04:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:26
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:52:07

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:41
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:50:26

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:41
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:50:26

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:41
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '14:24'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:50:26

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 14:24'	System	08 Apr 2021 17:50:26

**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:25:45
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 22:52:14



**US3092022**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 22:52:14

**US3092022**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:26:39

US3092022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User closed query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:00:02
Query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONFIRMED DATA CORRECT' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 23:27:56
User opened query 'Safety Call Day 239 'Date of Contact or Contact Attempt' is less than 207 days or greater than 213 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Apr 2021 23:26:39
User entered '05 Apr 2021'	(b) (4), (b) (6)	06 Apr 2021 23:26:39

**US3092022**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (D) (4), (b) (6)	06 Apr 2021 23:26:56
User entered 'Contact Not Made (CONTACT NOT MADE)'		06 Apr 2021 23:26:39

US3092022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:04:00

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	(b) (4) System	06 Apr 2021 23:26:56
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	06 Apr 2021 23:26:39
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 23:26:39

**US3092022**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 23:28:01

**US3092022**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 23:28:01

**US3092022**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:53:49



**US3092022**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:07
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:53:49

**US3092022**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:53:49

**US3092022**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:04:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:07
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:53:49

US3092022

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:04:00

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:53:54

**US3092022**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 21:53:54

**US3092022**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:17

**US3092022**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:17

**US3092022**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:17



**US3092022**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:04:00**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 19:22:17

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

**Date of updated informed consent (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		06 Apr 2021 15:59:06
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:23:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:32:29

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		06 Apr 2021 15:59:09
User signature succeeded.	Valentine Ebuh (b) (4)	05 Apr 2021 02:36:18
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:23:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:32:29

US3092022

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

Form: Unblinding

Generated On: 09 Jun 2021 15:04:00

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58

US3092022

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

Form: Unblinding

Generated On: 09 Jun 2021 15:04:00

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58



**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:43:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
User entered empty.	System	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:04:00**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
User entered empty.	System	20 Jan 2021 19:22:58

**US3092022**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:44:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:23:18

US3092022

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:04:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:44:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:23:18

**US3092022**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:44:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '12:20'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:23:18

**US3092022**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:04:00**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
User entered '20 Jan 2021 12:20'	System	20 Jan 2021 19:23:18



**US3092022**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:04:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:44:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:23:32

US3092022

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:04:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:44:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:44:15
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'updated' (Site from DM).	Heather Jimenez (b) (4) (b) (4)	05 Feb 2021 23:47:39
User entered '20 Jan 2021' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	05 Feb 2021 23:47:31
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 19JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 09:51:21
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 19:23:32

**US3092022**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:04:00**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
DataPoint Verified.		30 Mar 2021 19:44:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '12:18'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:23:32

**US3092022**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:04:00**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:21:19
User entered '20 Jan 2021 12:18'	System	05 Feb 2021 23:47:31
User entered '19 Jan 2021 12:18'	System	20 Jan 2021 19:23:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:04:00**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:20
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:18:06
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	29 Oct 2020 01:09:09

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:46:17
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:15
User entered 'USA-US086-2020-mRNA-1273-P301000004'	System	12 Nov 2020 22:59:00
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 22:59:00

US3092022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:46:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'PV Query: Was the SAE considered a worsening of the subject's medical history of dizziness, if yes, please update event term. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:06
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 09:27:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 09:27:52
Data point term sent to Coder	System	15 Dec 2020 22:57:36
Query 'PV Query: Was the SAE considered a worsening of the subject's medical history of dizziness, if yes, please update event term. ' answered with 'updated per query' (Site from Safety).	destiny robinson (b) (4) (b) (4)	15 Dec 2020 22:56:55
DataPoint Un-verified.	destiny robinson (b) (4) (b) (4)	15 Dec 2020 22:56:43
Coding entries removed.	destiny robinson (b) (4) (b) (4)	15 Dec 2020 22:56:43
User entered 'worsening DIZZINESS' reason for change: Per Query Resolution	destiny robinson (b) (4) (b) (4)	15 Dec 2020 22:56:43
User opened query 'PV Query: Was the SAE considered a worsening of the subject's medical history of dizziness, if yes, please update event term. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 00:05:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:16:02
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:19:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:19:37
Data point term sent to Coder	System	11 Nov 2020 22:18:35
User entered 'Dizziness'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:05
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:15
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:16
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:19
User entered '3 Oct 2020'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:21
User entered empty.	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:23
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:01:03
DataPoint Un-verified.		30 Mar 2021 19:07:04
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:26
User entered '6 Oct 2020'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:28
User entered empty.	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:18:32

US3092022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:47:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'PV Query: Since the subject was hospitalized for the event of Dizziness, please consider updating event severity to grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:47:14
Query 'PV Query: Since the subject was hospitalized for the event of Dizziness, please consider updating event severity to grade 4.' answered with 'After re-review, PI determined this AE to be a Grade 4' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 00:57:09
DataPoint Un-verified.	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 00:53:26
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 00:53:26
User opened query 'PV Query: Since the subject was hospitalized for the event of Dizziness, please consider updating event severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:05:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:16:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:31
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:42
User entered '0'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:43
User entered '0'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:16:45
User entered 'I'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:18:56
User entered '3 Oct 2020' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:20:25
User entered '3 Nov 2020'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

US3092022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:31
User closed query 'Per Medica Records, discharge date is 06Oct2020, please review and correct.' (Site from CRA).		14 Apr 2021 22:21:30
Query 'Per Medica Records, discharge date is 06Oct2020, please review and correct.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:20:54
DataPoint Un-verified.		09 Apr 2021 14:20:21
Signature has been broken.		09 Apr 2021 14:20:21
User entered '06 Oct 2020' reason for change: Data Entry Error		09 Apr 2021 14:20:21
DataPoint Verified.		06 Apr 2021 15:01:03
User opened query 'Per Medica Records, discharge date is 06Oct2020, please review and correct.' (Site from CRA).		06 Apr 2021 14:58:25
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 14:57:09
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:19:18
User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct.' (Site from System).	System	11 Nov 2020 22:20:25
Query 'Hospital discharge date is prior to Hospital admission date. Please correct.' answered by data change (Site from System).	System	11 Nov 2020 22:20:25
User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct.' (Site from System).	System	11 Nov 2020 22:18:32
User entered '5 Oct 2020'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:19:21
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:35
User entered empty.	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:36
User entered '0'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:38
User entered '0'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:40
User entered '0'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:42
User entered 'Not Related (NOT RELATED)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:43
User entered 'Not Related (NOT RELATED)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:45
User entered 'Not Applicable (NOT APPLICABLE)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:47:36
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	15 Dec 2020 22:57:13
User entered '1' reason for change: Data Entry Error	System	15 Dec 2020 22:57:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	destiny robinson (b) (4)	15 Dec 2020 22:57:13
User closed query 'Per DM CLR: Please verify if there were treatments given for this AE, as it required hospitalization, and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4)	15 Dec 2020 22:56:43
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Nov 2020 11:56:58
Query 'Per DM CLR: Please verify if there were treatments given for this AE, as it required hospitalization, and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'CONFIRMED AND CORRECTED EDC' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 21:12:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Vicki Martinez (b) (4)	23 Nov 2020 21:12:28
DataPoint Un-verified.	(b) (4)	23 Nov 2020 21:12:28
User entered '0' reason for change: Data Entry Error	Vicki Martinez (b) (4)	23 Nov 2020 21:11:40
User opened query 'Per DM CLR: Please verify if there were treatments given for this AE, as it required hospitalization, and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4)	23 Nov 2020 21:11:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:13:50
	(b) (4), (b) (6)	12 Nov 2020 17:21:56

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EAB) (1725)

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[None](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Vicki Martinez (b) (4)	11 Nov 2020 22:20:25
	(b) (4)	
User entered '0'	Vicki Martinez (b) (4)	11 Nov 2020 22:18:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:47:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
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).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:48:34
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 per query' (Site from DM).	destiny robinson (b) (4) (b) (4)	15 Dec 2020 22:57:01
User entered '0' reason for change: Data Entry Error	destiny robinson (b) (4)	15 Dec 2020 22:56:43
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) (4), (b) (6)	05 Dec 2020 11:42:42
DataPoint Un-verified.	Vicki Martinez (b) (4)	23 Nov 2020 21:12:48
User entered '1' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	23 Nov 2020 21:12:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:58
User entered '0' reason for change: Data Entry Error	Vicki Martinez (b) (4)	11 Nov 2020 22:20:25
User entered '1'	(b) (4) Vicki Martinez (b) (4)	11 Nov 2020 22:18:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:21:59
User entered '0'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:22:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:22:02
User entered empty.	Vicki Martinez (b) (4) (b) (4)	11 Nov 2020 22:18:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Per DM CLR: Narrative indication that he sustained a neck injury while in military. However, there is no corresponding MH record that match this information. Please update to record the MH condition as applicable. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 07:14:17
User closed query 'PV Query: Please add any relevant information and results for diagnostic test MRI and CT scan of neck mentioned in MR.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 15:47:45
User closed query 'PV Query: Per MR, subject had a positive wound culture for Staphylococcus infection. Please add all relevant information into EDC.' (Site from Safety).		25 Nov 2020 15:47:42
User closed query 'PV Query: Per MR, please provide additional information for right foot surgery, which was mentioned in MR "as recent as a week" prior to onset of event.' (Site from Safety).		25 Nov 2020 15:47:36
User closed query 'PV query: Please clarify the type of neck injury and the mechanism for dizziness .' (Site from Safety).		25 Nov 2020 15:47:31
User closed query 'PV query: Please clarify is subject has history of dizziness.' (Site from Safety).		25 Nov 2020 15:47:28
User closed query 'PV query: Please clarify the indication for the antibiotic therapy.' (Site from Safety).		25 Nov 2020 15:47:25
User closed query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).		25 Nov 2020 15:47:21
Query 'Per DM CLR: Narrative indication that he sustained a neck injury while in military. However, there is no corresponding MH record that match this information. Please update to record the MH condition as applicable. Otherwise, clarify.' answered with 'CONFIRMED AND COMPLETED' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:57:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:04:00

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add any relevant information and results for diagnostic test MRI and CT scan of neck mentioned in MR.' answered with 'NO EVIDENCE OF SIGNIFICANT STENOSIS' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:57:09
Query 'PV Query: Per MR, subject had a positive wound culture for Staphylococcus infection. Please add all relevant information into EDC.' answered with 'SUBJECT REPORTED A HISTORY OF STAPH FOOT INFECTION BUT NONE NOTED DURING EXAMINATION. NO DOCUMENTATION.' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:46:11
Query 'PV Query: Per MR, please provide additional information for right foot surgery, which was mentioned in MR "as recent as a week" prior to onset of event.' answered with 'HAS CHRONIC ROGHT FOOT RIGHT FOOT WOUIND AND HAS HA MULTIPLE SUGERIES.' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:44:18
Query 'PV query: Please clarify the type of neck injury and the mechanism for dizziness .' answered with 'Musculoskeletal NECK INJURY' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:43:02
Query 'PV query: Please clarify is subject has history of dizziness.' answered with 'CONFIRMED SUBJECT HAS A HISTORY OF DIZZINESS.' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:41:39
Query 'PV query: Please clarify the indication for the antibiotic therapy.' answered with 'PROPHYLAXIS INFECTION' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:41:17
Query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' answered with 'After PI consideration, Fall is not a separate AE.' (Site from Safety).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 00:57:59
User opened query 'Per DM CLR: Narrative indication that he sustained a neck injury while in military. However, there is no corresponding MH record that match this information. Please update to record the MH condition as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 21:15:27



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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add any relevant information and results for diagnostic test MRI and CT scan of neck mentioned in MR.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:05:13
User opened query 'PV Query: Per MR, subject had a positive wound culture for Staphylococcus infection. Please add all relevant information into EDC.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:05:05
User opened query 'PV Query: Per MR, please provide additional information for right foot surgery, which was mentioned in MR "as recent as a week" prior to onset of event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:04:49
User opened query 'PV query: Please clarify the type of neck injury and the mechanism for dizziness .' (Site from Safety).		20 Nov 2020 17:04:28
User opened query 'PV query: Please clarify is subject has history of dizziness.' (Site from Safety).		20 Nov 2020 17:04:21
User opened query 'PV query: Please clarify the indication for the antibiotic therapy.' (Site from Safety).		20 Nov 2020 17:04:15
User opened query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).		20 Nov 2020 17:04:06
DataPoint Verified.		12 Nov 2020 17:22:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:38:47
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 22:38:47
User entered 'Subject was hospitalized for dizziness causing him to fall. Subject was informed that it was due to a neck injury that he sustained while in the military. Subject was hospitalized for 2 days.' reason for change: Data Entry Error	Vicki Martinez (b) (4)	11 Nov 2020 22:38:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:18:32
User entered empty.	Vicki Martinez (b) (4)	11 Nov 2020 22:18:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:18:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:18:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 22:18:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
User closed query 'Subject discharge records documents Right Toe injury and Staph infection. Please add both AEs to AE log in EDC and Source.' (Site from CRA).		30 Dec 2020 15:49:38
Query 'Subject discharge records documents Right Toe injury and Staph infection. Please add both AEs to AE log in EDC and Source.' answered with 'RIGHT TOE INJURY CONFIRMED AND ADDED AS AN AE. STAPH- NOT ADDED AS AE PER PI.' (Site from CRA).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:33:00
User opened query 'Subject discharge records documents Right Toe injury and Staph infection. Please add both AEs to AE log in EDC and Source.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:41:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		30 Mar 2021 19:06:56
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Lethargy, LLT: Lethargy - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 20:24:35
Data point term sent to Coder	(b) (4)	
User entered 'lethargy'	System	12 Nov 2020 20:23:22
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22



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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '3 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
User entered empty.	System	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '6 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
User entered empty.	System	12 Nov 2020 20:23:22



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Per source Is the Adverse Event Serious is "Yes", please review and make necessary corrections.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 16:11:51
Query 'Per source Is the Adverse Event Serious is "Yes", please review and make necessary corrections.' answered with 'CONFIRMED AND CORRECTED ' (Site from CRA).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:14:30
User opened query 'Per source Is the Adverse Event Serious is "Yes", please review and make necessary corrections.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:32:45
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'l'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	12 Nov 2020 20:23:22

US3092022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:04:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 20:23:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	System	12 Nov 2020 20:23:33
Data Entry Error	destiny robinson (b) (4)	12 Nov 2020 20:23:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Nov 2020 20:23:22
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	12 Nov 2020 20:23:22
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
User entered '0'	System	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32
User entered '0'	System	12 Nov 2020 20:23:22

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:32



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		30 Mar 2021 19:07:31
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Toe injury - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	25 Nov 2020 02:42:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 02:42:08
Data point term sent to Coder	System	25 Nov 2020 02:41:07
User entered 'RIGHT TOE INJURY'	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		30 Mar 2021 19:07:33
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		30 Mar 2021 19:07:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		30 Mar 2021 19:07:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

US3092022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '22 Sep 2020' reason for change: Data Entry Error	System	25 Nov 2020 02:42:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Vicki Martinez (b) (4)	25 Nov 2020 02:42:38
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN Sep 2020' (non-conformant).	System	25 Nov 2020 02:41:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 02:41:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 02:41:18
User entered 'UN Sep 2020' (non-conformant).	Vicki Martinez (b) (4)	25 Nov 2020 02:41:18
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Nov 2020 02:41:09
User entered '00 Sep 2020' (non-conformant).	System	25 Nov 2020 02:41:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Vicki Martinez (b) (4)	25 Nov 2020 02:41:09
User entered ' Sep 2020' (non-conformant).	(b) (4)	
	System	25 Nov 2020 02:40:13
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
User entered empty.	System	25 Nov 2020 02:40:13



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '22 Sep 2020'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
User entered empty.	System	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

US3092022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

US3092022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4)	
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13

US3092022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.	(b) (4)	06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic 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)	08 Jan 2021 13:03:08
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic 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 'information has been correct and updated ' (Site from DM).	destiny robinson (b) (4)	15 Dec 2020 23:05:13
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic 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)	05 Dec 2020 11:43:02
User entered 'I'	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13

US3092022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:04:00

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	(b) (4)	
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	System	25 Nov 2020 02:40:49
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	Vicki Martinez (b) (4)	25 Nov 2020 02:40:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	System	25 Nov 2020 02:40:13
	Vicki Martinez (b) (4)	25 Nov 2020 02:40:13
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'SECOND METATARSAL REPLACEMENT'	(b) (4) Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:40:13



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'DUE TO MULTIPLE RIGHT FOOT FRACTURES THE SUBJECT HAS UNDERGONE SEVERAL SUGERIES.'	(b) (4) Vicki Martinez (b) (4)	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
User entered '0'	System	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39
User entered 'I'	System	25 Nov 2020 02:40:13

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:39

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 17:30:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:30:10
Data point term sent to Coder	System	04 Mar 2021 17:29:45
User entered 'right rotator cuff tear'	destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '15 Dec 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
User entered empty.	System	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '15 Dec 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	04 Mar 2021 17:29:40
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
User entered empty.	System	04 Mar 2021 17:29:40



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	04 Mar 2021 17:29:40
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	04 Mar 2021 17:29:40
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 21:03:32
Query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4)	15 Mar 2021 20:12:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	15 Mar 2021 20:12:13
User opened query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 11:57:19
User entered 'Not Applicable (NOT APPLICABLE)'	destiny robinson (b) (4)	04 Mar 2021 17:29:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded procedure of Right Rotator Cuff Reattachment. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).		25 Mar 2021 01:45:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded procedure of Right Rotator Cuff Reattachment. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'done' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	23 Mar 2021 22:40:06
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded procedure of Right Rotator Cuff Reattachment. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	Marissa Cervenka (b) (4)	23 Mar 2021 22:37:17
User entered '1'	(b) (4)	
	(b) (4), (b) (6)	20 Mar 2021 06:47:21
	destiny robinson (b) (4)	04 Mar 2021 17:29:40
	(b) (4)	



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

US3092022

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:04:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	23 Mar 2021 22:37:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	04 Mar 2021 17:29:40
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
User entered '0'	System	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48
User entered 'I'	System	04 Mar 2021 17:29:40

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:48



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal skin infection, LLT: Staphylococcal skin infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 08:38:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 08:38:54
Data point term sent to Coder	System	13 Mar 2021 19:16:00
Coding entries removed.	(b) (4), (b) (6)	13 Mar 2021 19:15:06
User entered 'RIGHT 2ND TOE STAPHALOCOCCUS INFECTION' reason for change: Data Entry Error		13 Mar 2021 19:15:06
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Staphylococcal skin infection, LLT: Staphylococcal skin infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 10:45:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 10:45:02
Data point term sent to Coder	System	04 Mar 2021 17:32:47
User entered '2nd toe staphalococcus infection'	destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

US3092022

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.	(b) (4)	06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Mar 2021 18:05:13
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 18:05:13
Comment added 'day is not known'.	Vicki Martinez (b) (4)	10 Mar 2021 23:12:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:39
User entered 'un Sep 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 23:10:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:24
User entered '00 Sep 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 23:10:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:16
User entered 'NK Sep 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 23:10:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:10:07
User entered 'UN Sep 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 23:10:07
Comment added 'DAY IS UNKNOWN'.	Vicki Martinez (b) (4)	10 Mar 2021 21:52:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 21:52:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 21:52:17

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered ' Sep 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 21:52:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	04 Mar 2021 17:32:14
User entered 'un Sep 2020' (non-conformant).	System	04 Mar 2021 17:32:14
	destiny robinson (b) (4)	04 Mar 2021 17:32:14
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
User entered empty.	System	04 Mar 2021 17:32:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.	(b) (4)	06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Mar 2021 18:05:13
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Mar 2021 18:05:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Mar 2021 22:26:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Mar 2021 22:26:40
User entered 'UN Oct 2020' (non-conformant).	(b) (4), (b) (6)	11 Mar 2021 22:26:40
Comment added 'day is not known'.	Vicki Martinez (b) (4)	10 Mar 2021 23:12:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:11:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 23:11:18
User entered 'un Nov 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 23:11:18
Comment added 'DAY IS UNKNOWN'.	Vicki Martinez (b) (4)	10 Mar 2021 21:52:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 21:52:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Mar 2021 21:52:17
User entered 'Nov 2020' (non-conformant).	Vicki Martinez (b) (4)	10 Mar 2021 21:52:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Mar 2021 17:32:14
User entered 'un Nov 2020' (non-conformant).	destiny robinson (b) (4)	04 Mar 2021 17:32:14

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	04 Mar 2021 17:32:14
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
User entered empty.	System	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

US3092022

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	04 Mar 2021 17:32:14
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4)	
	destiny robinson (b) (4)	04 Mar 2021 17:32:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

US3092022

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:04:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		25 Mar 2021 01:46:14
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'See concomitant medication log #6.' (Site from DM).	(b) (4)	
	Marissa Cervenka (b) (4)	23 Mar 2021 22:49:32
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 06:47:34
User entered 'I'	destiny robinson (b) (4)	04 Mar 2021 17:32:14
	(b) (4)	

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
User entered '0'	System	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55
User entered 'I'	System	04 Mar 2021 17:32:14

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:07:55

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00

US3092022

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:00

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User coded data point as SOC: Renal and urinary disorders, HLT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Mar 2021 23:40:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 23:40:54
Data point term sent to Coder	System	11 Mar 2021 23:40:40
User entered 'ACUTE KIDNEY INJURY'	(b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
User entered empty.	System	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
User entered empty.	System	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

US3092022

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:00

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).		25 Mar 2021 01:51:24
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
	(b) (4)	
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4)	23 Mar 2021 22:50:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	23 Mar 2021 22:50:49
	(b) (4)	
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:09:52
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Mar 2021 23:40:08



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
DataPoint Verified.		06 Apr 2021 15:01:03
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 23:40:08

US3092022

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:04:00

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
User closed query 'Per DM CLR: SAE Narrative = SUBJECT STOPPED LISINOPRIL. Review if CM#2 Lisinopril should reflect this. Review and update CM entry or provide clarification. ' (Site from DM).		15 Apr 2021 15:02:46
Query 'Per DM CLR: SAE Narrative = SUBJECT STOPPED LISINOPRIL. Review if CM#2 Lisinopril should reflect this. Review and update CM entry or provide clarification. ' answered with 'CM LOG UPDATED IN ECRF AND SOURCE' (Site from DM).	Marissa Cervenka (b) (4)	09 Apr 2021 21:02:46
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:01:03
User opened query 'Per DM CLR: SAE Narrative = SUBJECT STOPPED LISINOPRIL. Review if CM#2 Lisinopril should reflect this. Review and update CM entry or provide clarification. ' (Site from DM).		05 Apr 2021 07:36:34
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:53:26
User entered 'AS TREATMENT, SUBJECT STOPPED LISINOPRIL'	(b) (4), (b) (6)	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
User entered '0'	System	11 Mar 2021 23:40:08

**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00
User entered '1'	System	11 Mar 2021 23:40:08



**US3092022**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:08:00

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:04:00

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:20
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per source, subject took amoxicillin IV drip, please update con med log in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:47:44
Query 'Per source, subject took amoxicillin IV drip, please update con med log in EDC.' answered with 'updated in edc con med log ' (Site from CRA).	destiny robinson (b) (4)	19 Oct 2020 19:52:59
User opened query 'Per source, subject took amoxicillin IV drip, please update con med log in EDC.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:44:28
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:50:22
User entered 'Yes (Y)'	Robert Miranda (b) (4)	10 Aug 2020 14:59:46

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:06:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:06:14
Data point term sent to Coder	System	10 Aug 2020 15:02:10
User entered 'atorvastatin'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM). Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. answered with 'Updated' (Site from DM). User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Heather Jimenez (b) (4) (b) (4), (b) (6)	15 Oct 2020 10:39:48 22 Sep 2020 20:51:00 03 Sep 2020 08:09:22
User entered 'Hyperlipidemia'	(b) (4), (b) (6) Robert Miranda (b) (4) (b) (4)	13 Aug 2020 18:52:01 10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 10:55:03
Query 'Per DM CLR: Please review recorded Dose as destiny robinson this is not the usual dose for this medication. Please update as appropriate or provide clarification. ' answered with 'recorded as it was documented in chart ' (Site from DM).	(b) (4) (b) (4)	19 Oct 2020 19:49:01
User opened query 'Per DM CLR: Please review recorded Dose as this is not the usual dose for this medication. Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:51:46
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered '200'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'mg (mg)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39



US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'once daily (QD)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Oral (ORAL)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:42:12
User closed query 'Per source start date is UN/UNK/2018, please review and update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:41:14
Query 'Per source start date is UN/UNK/2018, please review and update.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4)	22 Sep 2020 20:51:52
	(b) (4)	
User entered 'UN UNK 2018' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:51:43
	(b) (4)	
User opened query 'Per source start date is UN/UNK/2018, please review and update.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:54:49
DataPoint Un-verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:08
DataPoint Verified.		13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:01:39
	(b) (4)	

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:42:14
User entered '0' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:51:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:11
DataPoint Verified.		13 Aug 2020 18:52:01
User entered '1'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39



US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:04:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:01:39

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:01:39

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
DataPoint Verified.		14 Apr 2021 22:14:32
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Apr 2021 14:49:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Apr 2021 14:49:41
Data point term sent to Coder	System	10 Apr 2021 14:48:51
Coding entries removed.	(b) (4), (b) (6)	10 Apr 2021 14:48:03
DataPoint Un-verified.		10 Apr 2021 14:48:03
Coding entries removed.		10 Apr 2021 14:48:03
Signature has been broken.		10 Apr 2021 14:48:03
User entered 'LISINOPRIL' reason for change: Data Entry Error		10 Apr 2021 14:48:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Aug 2020 00:07:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:07:57
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
Data point term sent to Coder	System	10 Aug 2020 15:03:11

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
User entered 'Lisinoprol'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
DataPoint Verified.		14 Apr 2021 22:14:33
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Apr 2021 14:48:03
Signature has been broken.		10 Apr 2021 14:48:03
User entered 'HYPERTENSION' reason for change: Data Entry Error		10 Apr 2021 14:48:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 10:40:46
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:52:06
' answered with 'Updated' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 08:09:45
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Hypertesion'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered '20'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'mg (mg)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'once daily (QD)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Oral (ORAL)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:42:05
User closed query 'Per source start date is UN/UNK/2018, please review and update.' (Site from CRA).		14 Oct 2020 15:40:55
Query 'Per source start date is UN/UNK/2018, please review and update.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:52:24
User entered 'UN UNK 2018' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:52:18
User opened query 'Per source start date is UN/UNK/2018, please review and update.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:55:09
DataPoint Un-verified.	(b) (4), (b) (6)	13 Aug 2020 18:55:00
DataPoint Verified.		13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06



US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User closed query 'Per AE Acute Kindney Injury, subject stopped Lisinoprol, please update End Date. IF subject restarted Lisinoprol, please add a new log line for Lisinoprol with new start date. Also, update con med log in source.' (Site from CRA).		14 Apr 2021 22:14:17
Query 'Per AE Acute Kindney Injury, subject stopped Lisinoprol, please update End Date. IF subject restarted Lisinoprol, please add a new log line for Lisinoprol with new start date. Also, update con med log in source.' answered with 'done' (Site from CRA).	Marissa Cervenka (b) (4)	09 Apr 2021 20:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 15:21:37
User opened query 'Per AE Acute Kindney Injury, subject stopped Lisinoprol, please update End Date. IF subject restarted Lisinoprol, please add a new log line for Lisinoprol with new start date. Also, update con med log in source.' (Site from CRA).		06 Apr 2021 15:12:02
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 15:08:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:42:06
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	22 Sep 2020 20:52:31
User entered '0' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:52:31
	(b) (4)	
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	22 Sep 2020 20:52:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Aug 2020 18:54:58
DataPoint Verified.		13 Aug 2020 18:52:01
User entered '1'	Robert Miranda (b) (4)	10 Aug 2020 15:03:06
	(b) (4)	

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
DataPoint Verified.	(b) (4)	14 Apr 2021 22:17:31
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4)	(b) (4)
Signature has been broken.	Marissa Cervenka (b) (4)	09 Apr 2021 20:47:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 20:47:48
DataPoint Verified.	Marissa Cervenka (b) (4)	09 Apr 2021 20:47:48
DataPoint Un-verified.	(b) (4)	06 Apr 2021 15:21:37
User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 15:08:24
DataPoint Verified.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Yes (Y)'	(b) (4)	(b) (4)
	(b) (4), (b) (6)	13 Aug 2020 18:52:01
	(b) (4)	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
DataPoint Verified.	(b) (4)	14 Apr 2021 22:17:32
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
DataPoint Un-verified.	(b) (4)	
	Marissa Cervenka (b) (4)	09 Apr 2021 20:47:48
Signature has been broken.	(b) (4)	
	Marissa Cervenka (b) (4)	09 Apr 2021 20:47:48
User entered '04 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	09 Apr 2021 20:47:48
User signature succeeded.	(b) (4)	
	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	(b) (4)	
	Robert Miranda (b) (4)	10 Aug 2020 15:03:06
	(b) (4)	

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:04:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:03:06

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User entered '1'	System	10 Aug 2020 15:03:06

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User entered '1'	System	10 Aug 2020 15:03:06

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:03
User entered '804 (804)'	System	10 Aug 2020 15:03:06

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 15:06:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 15:06:11
	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 15:05:16
User entered 'Clonazepam'	Robert Miranda (b) (4)	10 Aug 2020 15:05:05
	(b) (4)	



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 10:41:24
(Site from DM). Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:52:56
' answered with 'Updated' (Site from DM). User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.'	(b) (4), (b) (6)	03 Sep 2020 08:10:01
(Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Anxiety'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered '4'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'mg (mg)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'once daily (QD)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Oral (ORAL)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:41:57
User closed query 'Per source start date is UN/UNK/2017, please review and update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:41:24
Query 'Per source start date is UN/UNK/2017, please review and update.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4)	22 Sep 2020 20:53:11
	(b) (4)	
User entered 'UN UNK 2017' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:53:04
	(b) (4)	
User opened query 'Per source start date is UN/UNK/2017, please review and update.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:55:51
DataPoint Un-verified.	(b) (4), (b) (6)	13 Aug 2020 18:55:29
DataPoint Verified.		13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:05:05
	(b) (4)	

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:41:59
User entered '0' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:53:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:55:30
DataPoint Verified.		13 Aug 2020 18:52:01
User entered '1'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:04:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:05:05

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:05:05

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:05:05



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:05:05

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: ETODOLAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 03:59:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 03:59:44
Data point term sent to Coder Coding entries removed.	System Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:16:25 25 Nov 2020 01:16:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: ETODOLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:17:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:17:12
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
Data point term sent to Coder User entered 'etodolac'	System Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:07:21 10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:16:59
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR re-query: per response "done", however there is no change reflecting in eCRF kindly review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:03:39
Query 'Per DM CLR re-query: per response "done", however there is no change reflecting in eCRF kindly review and update as appropriate.' answered with 'CONFIRMED AND CORRECTED IN EDC' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:16:31
DataPoint Un-verified.	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:16:20
User entered 'LEFT SHOULDER PAIN' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 01:16:20
User opened query 'Per DM CLR re-query: per response "done", however there is no change reflecting in eCRF kindly review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:14:33
User closed query 'Per DM CLR: Please review Indication and please update to specify which shoulder (e.g. Left or Right or Bilateral shoulders) has pain. Please update and reconcile with MH eCRF record so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:14:33
Query 'Per DM CLR: Please review Indication and please update to specify which shoulder (e.g. Left or Right or Bilateral shoulders) has pain. Please update and reconcile with MH eCRF record so there would be an appropriate match. Otherwise, clarify. ' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	04 Nov 2020 06:09:04
User opened query 'Per DM CLR: Please review Indication and please update to specify which shoulder (e.g. Left or Right or Bilateral shoulders) has pain. Please update and reconcile with MH eCRF record so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:57:34

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:28:28
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Heather Jimenez (b) (4)	22 Sep 2020 20:53:45
' answered with 'Updated- shoulder surgery ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	(b) (4), (b) (6)	03 Sep 2020 08:10:12
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'shoulder pain'	Robert Miranda (b) (4)	10 Aug 2020 15:06:29
	(b) (4)	

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered '500'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'mg (mg)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29



US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'as needed (PRN)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Oral (ORAL)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:41:34
User closed query 'Per source start date is UN/UNK/2016, please review and update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:41:31
Query 'Per source start date is UN/UNK/2016, please review and update.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4)	22 Sep 2020 20:54:06
	(b) (4)	
User entered 'UN UNK 2016' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:54:00
	(b) (4)	
User opened query 'Per source start date is UN/UNK/2016, please review and update.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:56:21
DataPoint Un-verified.	(b) (4), (b) (6)	13 Aug 2020 18:56:03
DataPoint Verified.		13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:06:29
	(b) (4)	

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:41:36
User entered '0' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:54:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:56:05
DataPoint Verified.		13 Aug 2020 18:52:01
User entered '1'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 15:06:29

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 15:06:29

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:48:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:59:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:59:57
Data point term sent to Coder	System	10 Nov 2020 14:48:24
Coding entries removed.	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:48:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:57:43
Data point term sent to Coder	System	22 Sep 2020 20:56:32
DataPoint Un-verified.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:55:56
Coding entries removed.	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:55:56
User entered 'GABAPENTIN' reason for change: Data Entry Error	Heather Jimenez (b) (4) (b) (4)	22 Sep 2020 20:55:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:36:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:36:27
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Aug 2020 15:09:22
User entered 'Gahapentin'	Robert Miranda (b) (4)	10 Aug 2020 15:08:46
	(b) (4)	

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR: Please review Indication and please update to specify the location (anatomical body part) and specify the type of Neuropathy (e.g. Motor or Sensory). Please update and reconcile with MH eCRF record so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:14:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:48:36
Query 'Per DM CLR: Please review Indication and please update to specify the location (anatomical body part) and specify the type of Neuropathy (e.g. Motor or Sensory). Please update and reconcile with MH eCRF record so there would be an appropriate match. Otherwise, clarify. ' answered with 'done ' (Site from DM).	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:48:17
DataPoint Un-verified.	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:48:11
User entered 'NEUROPATHY Bilateral feet' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:48:11
User closed query 'Per CDM, per DM CLR re-query: Response noted; however, please, if possible, at the next patient contact, ensure the specific type/location of NEUROPATHY is recorded. Please review, update as appropriate and reconcile with Med History eCRF, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 20:50:52
User opened query 'Per DM CLR: Please review Indication and please update to specify the location (anatomical body part) and specify the type of Neuropathy (e.g. Motor or Sensory). Please update and reconcile with MH eCRF record so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:58:17



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM, per DM CLR re-query: Response noted; however, please, if possible, at the next patient contact, ensure the specific type/location of NEUROPATHY is recorded. Please review, update as appropriate and reconcile with Med History eCRF, else clarify. Thank you. ' answered with 'will collect at next contact. reached out to patient 10/28/20 no answer ' (Site from DM).	destiny robinson (b) (4) (b) (4)	29 Oct 2020 00:45:53
User opened query 'Per CDM, per DM CLR re-query: Response noted; however, please, if possible, at the next patient contact, ensure the specific type/location of NEUROPATHY is recorded. Please review, update as appropriate and reconcile with Med History eCRF, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:30:45
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:30:45
Query 'Per DM CLR: Please update the indication to reflect the location and type of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' answered with 'does not specify in chart ' (Site from DM).	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:49:53
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 08:10:28
DataPoint Verified.	(b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'neuropathy'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered '150'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'mg (mg)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'twice daily (BID)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Oral (ORAL)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46



US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 15:41:44
User closed query 'Per source start date is UN/UNK/2016, please review and update.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:41:42
Query 'Per source start date is UN/UNK/2016, please review and update.' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4)	22 Sep 2020 20:54:48
	(b) (4)	
User entered 'UN UNK 2016' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:54:38
	(b) (4)	
User opened query 'Per source start date is UN/UNK/2016, please review and update.' (Site from CRA).	(b) (4), (b) (6)	13 Aug 2020 18:56:41
DataPoint Un-verified.	(b) (4), (b) (6)	13 Aug 2020 18:56:31
DataPoint Verified.		13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:08:46
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:41:47
User entered '0' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:54:38
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:56:29
DataPoint Verified.		13 Aug 2020 18:52:01
User entered '1'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:52:01
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 15:08:46

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 15:08:46



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: COMBINATIONS OF ANTIBACTERIALS, ATC: COMBINATIONS OF ANTIBACTERIALS, PRODUCT: CEFTRIAXONE;VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:24:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:17:45
Data point term sent to Coder	System	23 Mar 2021 22:44:22
Coding entries removed.	Marissa Cervenka (b) (4) (b) (4)	23 Mar 2021 22:44:21
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Mar 2021 22:38:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: COMBINATIONS OF ANTIBACTERIALS, ATC: COMBINATIONS OF ANTIBACTERIALS, PRODUCT: CEFTRIAXONE;VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:14:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:14:44
Data point term sent to Coder	System	13 Mar 2021 18:59:57
Coding entries removed.	(b) (4), (b) (6)	13 Mar 2021 18:59:35
DataPoint Un-verified.		13 Mar 2021 18:59:35
Coding entries removed.		13 Mar 2021 18:59:35
Signature has been broken.		13 Mar 2021 18:59:35
User entered 'IV DRIP VANCOMYCIN/ROCEPHIN' reason for change: Data Entry Error		13 Mar 2021 18:59:35
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:23:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:44:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:44:56
Data point term sent to Coder	System	25 Nov 2020 02:45:08
Coding entries removed.	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:44:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:49:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:59:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:59:58
Data point term sent to Coder	System	10 Nov 2020 14:51:28
User entered 'amoxicillin' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:50:54
Data point term sent to Coder	System	10 Nov 2020 14:49:25
Coding entries removed.	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:49:00
User entered 'IV Drip' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	10 Nov 2020 14:49:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:06:32

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[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 'amoxicillin'	Coder Import (b) (4) (b) (4) System destiny robinson (b) (4) (b) (4)	19 Oct 2020 22:06:32  19 Oct 2020 19:52:54 19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
DataPoint Verified.	(b) (4)	14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded that matches this medication. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 07:39:18
Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded that matches this medication. Please update as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4)	09 Apr 2021 21:03:52
DataPoint Un-verified.	(b) (4)	09 Apr 2021 21:03:46
Signature has been broken.	Marissa Cervenka (b) (4)	09 Apr 2021 21:03:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 21:03:46
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is an AE recorded that matches this medication. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 13:44:16
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:49:11
User entered 'Yes (Y)'	destiny robinson (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
DataPoint Verified.	(b) (4)	06 Apr 2021 15:17:47
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:49:04
Signature has been broken.	(b) (4) Marissa Cervenka (b) (4)	23 Mar 2021 22:44:21
User entered 'RIGHT 2ND TOE STAPHALOCOCCUS INFECTION' reason for change: Data Entry Error	(b) (4) Marissa Cervenka (b) (4)	23 Mar 2021 22:44:21
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:59:35
User entered 'PROPHYLAXIS INFECTION RIGHT TOE INJURY' reason for change: Data Entry Error	(b) (4)	13 Mar 2021 18:59:35
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User closed query 'Per DM CLR re-query: Per response " foot injury prophylaxis infection" please update the same in the indication field else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:04:20
Query 'Per DM CLR re-query: Per response " foot injury prophylaxis infection" please update the same in the indication field else clarify.' answered with 'CONFIRMED AND CORRECTED' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:44:38
DataPoint Un-verified.	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:44:27
User entered 'RIGHT TOE INJURY PROPHYLAXIS INFECTION' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	25 Nov 2020 02:44:27
User opened query 'Per DM CLR re-query: Per response " foot injury prophylaxis infection" please update the same in the indication field else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:22:50
User closed query 'Per DM CLR: Please update the condition to include the type and location of Infection (e.g. etiology of infection, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:22:50

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:49:12
Query 'Per DM CLR: Please update the condition to include the type and location of Infection (e.g. etiology of infection, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' answered with 'foot injury prophylaxis infection ' (Site from DM).	destiny robinson (b) (4)	10 Nov 2020 14:50:43
User opened query 'Per DM CLR: Please update the condition to include the type and location of Infection (e.g. etiology of infection, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' (Site from DM).	(b) (4)	
User entered 'infection'	(b) (4), (b) (6)	02 Nov 2020 06:42:27
	destiny robinson (b) (4)	19 Oct 2020 19:52:19
	(b) (4)	

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:14
User entered 'unk'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:16
User entered 'Other (OTHER)'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19



US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:17
User entered 'unknown'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:18
User entered 'unknown (UNKNOWN)'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:20
User entered empty.	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:08
User entered 'Intravenous (INTRAVENOUS)'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:22
User entered empty.	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:23
User entered '3 Oct 2020'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:49:26
User entered '0'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:50:23
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:50:24
User entered '6 Oct 2020'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:04:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:50:26
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	19 Oct 2020 19:52:19

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User entered empty.	System	19 Oct 2020 19:52:19

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User entered empty.	System	19 Oct 2020 19:52:19

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:19
User entered empty.	System	19 Oct 2020 19:52:19

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:34
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Mar 2021 06:26:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:26:52
Data point term sent to Coder	System	13 Mar 2021 18:56:55
User entered 'MORPHINE'	(b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'RIGHT FOOT PAIN'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '03 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
DataPoint Verified.		06 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:38:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
User entered empty.	System	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
User entered empty.	System	13 Mar 2021 18:56:52

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:25
User entered empty.	System	13 Mar 2021 18:56:52

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:23
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 20:50:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 20:50:48
Data point term sent to Coder User entered 'Lisinopril'	System Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:49:53 09 Apr 2021 20:49:10



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:25
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:27
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Hypertension'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:28
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '20'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'mg (mg)'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:32
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:33
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'once daily (QD)'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:35
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:36
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Oral (ORAL)'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:38
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:39
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '6 Oct 2020'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:41
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:42
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:43
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:18:45
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	Marissa Cervenka (b) (4)	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 20:49:10

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 20:49:10



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 20:49:10

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Apr 2021 13:47:32
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 13:47:32
Data point term sent to Coder	System	09 Apr 2021 20:52:59
User entered 'AMOXICILLIN/POTASSIUM'	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'RIGHT 2ND TOE STAPHALOCOCCUS INFECTION'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '875/125'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'mg (mg)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'twice daily (BID)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Oral (ORAL)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '6 Oct 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '13 Oct 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:52:45



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
User entered '2'	System	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
User entered '1'	System	09 Apr 2021 20:52:45

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:15:57
User entered '804 (804)'	System	09 Apr 2021 20:52:45

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:04:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 07:21:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:21:50
Data point term sent to Coder	System	09 Apr 2021 20:54:01
User entered 'DOXYCYCLINE HYCLATE'	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'RIGHT 2ND TOE STAPHALOCOCCUS INFECTION'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '100'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:04:00

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'mg (mg)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'twice daily (BID)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Oral (ORAL)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '06 Oct 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '13 Oct 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
User entered '2'	System	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
User entered '1'	System	09 Apr 2021 20:53:51

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:21
User entered '804 (804)'	System	09 Apr 2021 20:53:51

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:00

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 08:07:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:07:15
Data point term sent to Coder	System	09 Apr 2021 21:01:07
User entered 'LIDOCAINE PATCH'	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'RIGHT 2ND TOE STAPHALOCOCCUS INFECTION'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'UNKNOWN'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Other (OTHER)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'UNKNOWN'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'other (OTHER)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '1 PATCH DAILY'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Topical (TOPICAL)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '6 Oct 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Apr 2021 16:04:36
User entered '13 Oct 2020'	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
User entered empty.	System	09 Apr 2021 21:00:27

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
User entered empty.	System	09 Apr 2021 21:00:27

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:04:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:19:00
User entered empty.	System	09 Apr 2021 21:00:27

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:00

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 07:08:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:08:56
Data point term sent to Coder	System	09 Apr 2021 21:02:09
User entered 'DICLOFENAC SODIUM'	Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'RIGHT 2ND TOE STAPHALOCOCCUS INFECTION'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '4'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'g (g)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

US3092022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:04:00

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'four times daily (QID)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'Topical (TOPICAL)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered empty.	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '6 Oct 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '5 Nov 2020'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
DataPoint Verified.		14 Apr 2021 22:19:30
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'No (N)'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
User entered '4'	System	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
User entered '1'	System	09 Apr 2021 21:01:49



**US3092022**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:04:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:16:15
User entered '804 (804)'	System	09 Apr 2021 21:01:49

**US3092022**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 15:04:00**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:20
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:38:36
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 15:10:47

US3092022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:00

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:02:55
User closed query 'Subject reported having right toe surgery, please update Con Med Procedures and AE log.' (Site from CRA).		23 Feb 2021 16:23:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Query 'Subject reported having right toe surgery, please update Con Med Procedures and AE log.' answered with 'CONFIRMED AND COMPLETED' (Site from CRA).	(b) (4) Vicki Martinez (b) (4)	25 Nov 2020 02:49:32
User entered '22 Sep 2020' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 02:48:49
User closed query 'Please remove Left Shoulder as this is medical history.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:41:23
User opened query 'Subject reported having right toe surgery, please update Con Med Procedures and AE log.' (Site from CRA).		18 Nov 2020 17:40:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 10:37:48
Query 'Data is required. Please complete.' answered with 'data removed per query request ' (Site from System).	destiny robinson (b) (4)	19 Oct 2020 19:57:56
Query 'Please remove Left Shoulder as this is medical history.' answered with 'data removed per query request ' (Site from CRA).	destiny robinson (b) (4)	19 Oct 2020 19:57:53
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 19:57:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 19:57:39
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	19 Oct 2020 19:57:39
User opened query 'Please remove Left Shoulder as this is medical history.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:40:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 20:59:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 20:59:10
User entered ' 2012' (non-conformant).	Heather Jimenez (b) (4)	22 Sep 2020 20:59:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	22 Sep 2020 20:57:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:00

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 20:57:31
User entered 'UN 2012' (non-conformant).	Heather Jimenez (b) (4)	22 Sep 2020 20:57:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 20:57:09
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:57:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:57:09
User entered ' 2012' (non-conformant).	Heather Jimenez (b) (4)	22 Sep 2020 20:57:09
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 15:11:35
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:11:35

US3092022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:02:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'SECOND METATARSAL REPLACEMENT' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 02:48:49
User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review to record the actual procedure done ensuring underlying condition is recorded in either the AE/Medhistory eCRF page. Reconcile as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:38:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 10:38:08
Query 'Data is required. Please complete.' answered with 'data removed per query request ' (Site from System).	destiny robinson (b) (4)	19 Oct 2020 19:58:05
Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review to record the actual procedure done ensuring underlying condition is recorded in either the AE/Medhistory eCRF page. Reconcile as appropriate, otherwise clarify.' answered with 'data removed per query request ' (Site from DM).	destiny robinson (b) (4)	19 Oct 2020 19:58:01
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 19:57:39
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	19 Oct 2020 19:57:39
User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please review to record the actual procedure done ensuring underlying condition is recorded in either the AE/Medhistory eCRF page. Reconcile as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:37:31
User entered 'Left Shoulder'	Robert Miranda (b) (4)	10 Aug 2020 15:11:35

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:03:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 02:48:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 10:38:10
Query 'Data is required. Please complete.' answered with 'data removed per query request ' (Site from System).	destiny robinson (b) (4)	19 Oct 2020 19:58:12
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 19:57:39
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	19 Oct 2020 19:57:39
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:57:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:57:09
User entered 'Medical History (MH)' reason for change: Data Entry Error	Heather Jimenez (b) (4)	22 Sep 2020 20:57:09
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 15:11:35
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:11:35

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:04:00

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:03:05
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered empty.	Robert Miranda (b) (4)	10 Aug 2020 15:11:35

US3092022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:00

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:33
DataPoint Verified.		06 Apr 2021 15:03:22
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:17:21
User entered '15 Dec 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	26 Feb 2021 17:10:34



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:00

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:33
DataPoint Verified.		06 Apr 2021 15:03:25
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:17:21
User entered 'RIGHT ROTATOR CUFF REATTACHMENT'	(b) (4) destiny robinson (b) (4) (b) (4)	26 Feb 2021 17:10:34

US3092022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:04:00

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:33
DataPoint Verified.		06 Apr 2021 15:03:28
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).		25 Mar 2021 02:19:20
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'See Concomitant Procedure #6.' (Site from DM).	Marissa Cervenka (b) (4)	23 Mar 2021 22:39:10
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:25:29
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:17:21
User entered 'Adverse Event (AE)'	(b) (4) destiny robinson (b) (4) (b) (4)	26 Feb 2021 17:10:34

**US3092022**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:04:00**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:03:33
DataPoint Verified.		06 Apr 2021 15:03:31
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:17:21
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	26 Feb 2021 17:10:34

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	(b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	System	25 Nov 2020 19:34:33
reason for change: Data Entry Error	Vicki Martinez (b) (4)	
User entered (b) (6)	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.		
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00



US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00
(non-conformant).		

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	(b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	System	25 Nov 2020 19:34:33
reason for change: Data Entry Error	Vicki Martinez (b) (4)	
User entered (b) (6)	(b) (4)	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	System	24 Nov 2020 21:37:40
change: Data Entry Error	Robert Miranda (b) (4)	
Un-reviewed for Safety.	(b) (4)	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.		
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00
(non-conformant).		

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered '12/Nov/2020 17:59'	System	12 Nov 2020 22:59:42

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'I'		12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	(b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	System	25 Nov 2020 19:34:33
reason for change: Data Entry Error	Vicki Martinez (b) (4)	
User entered (b) (6)	(b) (4)	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	System	24 Nov 2020 21:37:40
change: Data Entry Error	Robert Miranda (b) (4)	
Un-reviewed for Safety.	(b) (4)	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.		
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

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Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6) (non-conformant).	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '24/Nov/2020 15:54'	(b) (4) System	24 Nov 2020 20:54:12

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 15:58:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:12

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	(b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	System	25 Nov 2020 19:34:33
reason for change: Data Entry Error	Vicki Martinez (b) (4)	
User entered (b) (6)	(b) (4)	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	System	24 Nov 2020 21:37:40
change: Data Entry Error	Robert Miranda (b) (4)	
Un-reviewed for Safety.	(b) (4)	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.		
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01



US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00
(non-conformant).		

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '25/Nov/2020 10:42'	(b) (4) System	25 Nov 2020 15:42:39

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 15:58:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:42:39

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	System (b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00



US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6) (non-conformant).	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:58:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '16/Dec/2020 09:28'	(b) (4) System	16 Dec 2020 15:28:58

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 15:58:38
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 15:28:58



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	(b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	System	25 Nov 2020 19:34:33
reason for change: Data Entry Error	Vicki Martinez (b) (4)	
User entered (b) (6)	(b) (4)	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	System	24 Nov 2020 21:37:40
change: Data Entry Error	Robert Miranda (b) (4)	
Un-reviewed for Safety.	(b) (4)	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.		
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00

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Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
	(b) (4)	
User entered (b) (6)	System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

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Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00
(non-conformant).		

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '09/Apr/2021 15:48'	(b) (4) System	09 Apr 2021 19:48:58

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
User entered 'I'		09 Apr 2021 19:48:58

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	(b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	System	25 Nov 2020 19:34:33
reason for change: Data Entry Error	Vicki Martinez (b) (4)	
User entered (b) (6)	(b) (4)	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	System	24 Nov 2020 21:37:40
change: Data Entry Error	Robert Miranda (b) (4)	
Un-reviewed for Safety.	(b) (4)	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.		
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

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Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

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[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00



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Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6) (non-conformant).	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '12/Apr/2021 08:42'	(b) (4) System	12 Apr 2021 12:42:44

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
User entered 'I'		12 Apr 2021 12:42:44

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:05
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:39
Un-reviewed for Safety.		09 Apr 2021 19:48:36
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'USA-US086-2020-MRNA-1273-P301000004'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00



**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Yes (Y)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'No (N)'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Valentine'	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'Ebuh'	System	12 Nov 2020 22:59:00



US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:03
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '2701 S Hampton Road, Suite 250'	System (b) (4)	16 Dec 2020 15:28:58
User entered '2701 S. Hampton Road, Suite 250'	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '2701 S. Hampton Road' reason for	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered 'Dallas' reason for change: Data Entry Error	(b) (4)	
User entered (b) (6)	System	25 Nov 2020 15:42:39
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4)	
User entered (b) (6)	System	24 Nov 2020 20:54:12
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Un-verified.	(b) (4)	
User entered 'Dallas' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:17:59
User entered (b) (6)		12 Nov 2020 22:59:28
	System	12 Nov 2020 22:59:00

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered 'TX'	System	12 Nov 2020 22:59:00

US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:21:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:21:41
Un-reviewed for Safety.		14 Apr 2021 22:20:29
Signature has been broken.		14 Apr 2021 22:20:29
User entered '75224' reason for change: Data Entry Error		14 Apr 2021 22:20:29
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
Reviewed for Safety.		12 Apr 2021 14:47:56
Un-reviewed for Safety.	System	09 Apr 2021 19:48:58
DataPoint Un-verified.	System	09 Apr 2021 19:48:58
Signature has been broken.	System	09 Apr 2021 19:48:58
User entered (b) (6)	System	09 Apr 2021 19:48:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 19:48:28
DataPoint Verified.		06 Apr 2021 14:55:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
User entered '75224' reason for change: Data Entry Error	(b) (4) Vicki Martinez (b) (4)	16 Dec 2020 19:06:46
User entered (b) (6)	(b) (4) System	16 Dec 2020 15:28:58
(non-conformant).		
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	25 Nov 2020 19:34:33
User entered (b) (6)	(b) (4) System	25 Nov 2020 15:42:39
(non-conformant).		
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	24 Nov 2020 21:37:40
Un-reviewed for Safety.	(b) (4) System	24 Nov 2020 20:54:12
User entered (b) (6)	System	24 Nov 2020 20:54:12
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:54:01

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Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:04:00

Site Address: Postal Code

Audit	User	Time (GMT)
Un-reviewed for Safety.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
DataPoint Un-verified.	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
	(b) (4)	
User entered '75244' reason for change: Data Entry Error	Robert Miranda (b) (4)	23 Nov 2020 21:49:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:17:59
Reviewed for Safety.		12 Nov 2020 22:59:28
User entered (b) (6)	System	12 Nov 2020 22:59:00
(non-conformant).		

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 14:48:09
Un-reviewed for Safety.		12 Apr 2021 14:48:01
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:54:01
DataPoint Verified.		18 Nov 2020 17:17:59
User entered 'US'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:04:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	12 Apr 2021 14:48:22
User entered '6'	System	12 Apr 2021 12:42:44
User entered '5'	System	09 Apr 2021 19:48:58
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:23:25
	(b) (4)	
User entered '4'	System	16 Dec 2020 15:28:58
User entered '3'	System	25 Nov 2020 15:42:39
User entered '2'	System	24 Nov 2020 20:54:12
User entered '1'	System	12 Nov 2020 22:59:42

**US3092022**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:04:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered '12/Apr/2021 10:48'	(b) (4) System	12 Apr 2021 14:48:22



US3092022

Folder: SAE USA-US086-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:04:00

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:21:48
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:55:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:48:22