

US3312008 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:00:53

All time stamps listed in this document are displayed in GMT

US3312008

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

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Participant ID

US3312008

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

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US3312008

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 10 AUG 2020

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

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Folder OID SCRN

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US3312008

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Date of Birth (MMM yyyy)	(b) (6) 1933
Age	86
Age Units	YEARS
Age (Derived)	87
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	_____
Unknown	False
Not reported	False

US3312008

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Date of Informed Consent (*dd MMM yyyy*) 10 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3312008

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Did the participant meet all eligibility criteria?

Yes

No

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US3312008

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Were any significant conditions reported?

Yes

No

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US3312008

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3312008

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	ALLERGY TO BETA BLOCKERS
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312008

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	ALLERGY TO ACE INHIBITORS
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312008

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312008

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	BEE STING ALLERGY
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

US3312008

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	TOTAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3312008

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	RIGHT NEPHRECTOMY
Start date (dd MMM yyyy)	04 JUL 1960
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)	04 JUL 1960
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JUL 1960
Stop Year (derived)	1960

US3312008

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	RUPTURED BENIGN HEMATOMA ON RIGHT KIDNEY
Start date (dd MMM yyyy)	04 JUL 1960
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)	04 JUL 1960
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JUL 1960
Stop Year (derived)	1960

US3312008

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	LAMINECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3312008

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	RUPTURED DISC
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3312008

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	BACK COMPRESSION 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

US3312008

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3312008

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	LEFT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN OCT 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 OCT 2012
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2012
Start Year (derived)	2012
Stop Month and Year (derived)	OCT 2012
Stop Year (derived)	2012

US3312008

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	RIGHT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN OCT 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 OCT 2015
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2015
Start Year (derived)	2015
Stop Month and Year (derived)	OCT 2015
Stop Year (derived)	2015

US3312008

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	OSTEOPOROSIS BILATERAL HIPS
Start date (dd MMM yyyy)	UN JAN 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 JAN 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

US3312008

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312008

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312008

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	LEFT TOTAL MASTECTOMY
Start date (dd MMM yyyy)	13 MAR 1996
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)	13 MAR 1996
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1996
Start Year (derived)	1996
Stop Month and Year (derived)	MAR 1996
Stop Year (derived)	1996

US3312008

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	LEFT BREAST CANCER
Start date (dd MMM yyyy)	UN DEC 1995
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)	13 MAR 1996
Stop date completely unknown	False
Start Month and Year (derived)	DEC 1995
Start Year (derived)	1995
Stop Month and Year (derived)	MAR 1996
Stop Year (derived)	1996

US3312008

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	LEFT ARM LYMPHEDEMA
Start date (dd MMM yyyy)	UN SEP 1997
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)	SEP 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3312008

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	HAY FEVER
Start date (dd MMM yyyy)	UN UNK 1958
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 1960
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1960
Stop Year (derived)	1960

US3312008

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	04 JUL 1960
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)	04 JUL 1960
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JUL 1960
Stop Year (derived)	1960

US3312008

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Condition	DIFFICULTY SLEEPING
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)	

US3312008

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 10 AUG 2020

Time of assessment (00:00-23:59) 12:15 (24 HR)

Vital Signs Date and Time (derived) 10 AUG 2020 12:15

Height (xxx.x) 61.0 in

Weight (xxx.x) 154.8 lb

BMI (xxx.x) 29.31036 kg/m<sup>2</sup>

BMI units KG/M2

Temperature (xxx.x) ND - Not Done

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) ND - Not Done

Pulse units BPM

Respiratory Rate (xxx) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3312008

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

10 AUG 2020

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

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US3312008

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes   
No

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1970

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

US3312008

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

**Specify** \_\_\_\_\_

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3312008

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	True
<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)	False
<b>Other</b>	True
<b>Specify</b>	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

US3312008

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 10 AUG 2020

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

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Folder OID VISIT1

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US3312008

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185427

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

Human Immunodeficiency Virus (HIV) infection Yes  No

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Height	ND - Not Done
Weight	ND - Not Done

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US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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 ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	12:15 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:15
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	53 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	81 mmHg
Diastolic Blood Pressure units	MMHG

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:18 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:18
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	57 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	62 mmHg
Diastolic Blood Pressure units	MMHG

US3312008

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

10 AUG 2020

---

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

---

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 13:47 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 13:47

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

US3312008

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	10 AUG 2020
Collection time ( <i>00:00-23:59</i> )	13:16 (24 HR)
Collection date and time (derived)	10 AUG 2020 13:16

---

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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Collection date ( <i>dd MMM yyyy</i> )			10 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:47	10 AUG 2020 12:47
Nasopharyngeal Swab 2	No		

---

US3312008

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**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 97.9 °F

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

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

PC Time Stamp 10 AUG 2020 14:17

PC Open Date & Time 10 AUG 2020 14:07

PC Close Date & Time 10 AUG 2020 16:37

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	10 AUG 2020 19:54
PC Open Date & Time	10 AUG 2020 17:32
PC Close Date & Time	11 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 AUG 2020 18:19
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 AUG 2020 20:45
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**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** 96.7 °F

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

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

PC Time Stamp 13 AUG 2020 16:12

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 15:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 AUG 2020 15:44
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 AUG 2020 16:39
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**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	10 AUG 2020 14:18
PC Open Date & Time	10 AUG 2020 14:07
PC Close Date & Time	10 AUG 2020 16:37

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 AUG 2020 19:54

PC Open Date & Time

10 AUG 2020 17:32

PC Close Date & Time

11 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 2

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	11 AUG 2020 18:19
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 3

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

12 AUG 2020 20:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 4

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

13 AUG 2020 16:13

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 5

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

14 AUG 2020 15:14

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 6

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

15 AUG 2020 15:44

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 7

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	16 AUG 2020 16:40
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

No

Yes

---

PC Time stamp	10 AUG 2020 14:19
PC Open Date & Time	10 AUG 2020 14:07
PC Close Date & Time	10 AUG 2020 16:37

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

No   
Yes

---

PC Time stamp	10 AUG 2020 19:54
PC Open Date & Time	10 AUG 2020 17:32
PC Close Date & Time	11 AUG 2020 11:59

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

---

	Yes <input type="checkbox"/>
PC Time stamp	11 AUG 2020 18:20
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

---

	Yes <input type="checkbox"/>
PC Time stamp	12 AUG 2020 20:46
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

---

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 16:13
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

---

Yes

---

PC Time stamp	14 AUG 2020 15:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

---

Yes

---

PC Time stamp	15 AUG 2020 15:45
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

---

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

---

	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 16:40
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

---

US3312008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 7 SEP 2020

---

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

---

Folder OID VISIT2

---

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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 ( <i>dd MMM yyyy</i> )	07 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:57 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 12:57
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	67 mmHg
Diastolic Blood Pressure units	MMHG

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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)	07 SEP 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	07 SEP 2020 14:19
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3312008

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

07 SEP 2020

---

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

---

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

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) 7 SEP 2020

What was the treatment time? (00:00-23:59) 13:48 (24 HR)

Treatment Date and Time (derived) 7 SEP 2020 13:48

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

US3312008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 07 SEP 2020

---

Collection time (*00:00-23:59*) 13:15 (24 HR)

---

Collection date and time (derived) 07 SEP 2020 13:15

---

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Collection date ( <i>dd MMM yyyy</i> )			07 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:09	07 SEP 2020 13:09
Nasopharyngeal Swab 2	No		

---

US3312008

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 07 SEP 2020 15:17

PC Open Date & Time 07 SEP 2020 14:08

PC Close Date & Time 07 SEP 2020 16:38

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**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** 98.1 °F

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

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

PC Time Stamp 07 SEP 2020 18:12  
PC Open Date & Time 07 SEP 2020 17:33  
PC Close Date & Time 08 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	08 SEP 2020 17:42
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	09 SEP 2020 16:15
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

PC Time Stamp 10 SEP 2020 16:53

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 16:55
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 19:21
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 SEP 2020 18:22
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**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

07 SEP 2020 15:18

PC Open Date & Time

07 SEP 2020 14:08

PC Close Date & Time

07 SEP 2020 16:38

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

07 SEP 2020 18:13

PC Open Date & Time

07 SEP 2020 17:33

PC Close Date & Time

08 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 2

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)**

100

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)**

1

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

08 SEP 2020 17:43

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 3

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

1

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

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

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

09 SEP 2020 16:17

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 4

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

None

Please select one response below

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

10 SEP 2020 16:54

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 5

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

11 SEP 2020 16:56

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 6

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

12 SEP 2020 19:21

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 7

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

13 SEP 2020 18:22

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

No

Yes

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PC Time stamp	07 SEP 2020 15:18
PC Open Date & Time	07 SEP 2020 14:08
PC Close Date & Time	07 SEP 2020 16:38

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

No   
Yes

---

PC Time stamp	07 SEP 2020 18:13
PC Open Date & Time	07 SEP 2020 17:33
PC Close Date & Time	08 SEP 2020 11:59

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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	Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 17:44
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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	Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 16:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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	Yes <input type="checkbox"/>
PC Time stamp	10 SEP 2020 16:54
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

---

	Yes <input type="checkbox"/>
PC Time stamp	11 SEP 2020 16:56
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 19:22
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

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US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**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

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

---

	Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 18:22
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

---

US3312008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 21:37:45

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:24

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 21:37:46

Generated On: 09 Jun 2021 17:00:53

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 5 OCT 2020

---

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

---

Folder OID VISIT3

---

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 21:37:46

Generated On: 09 Jun 2021 17:00:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	5 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:15 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 13:15
Temperature ( <i>xxx.x</i> )	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	56 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312008

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 21:37:46

Generated On: 09 Jun 2021 17:00:53

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

5 OCT 2020

---

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

---

US3312008

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 21:37:46

Generated On: 09 Jun 2021 17:00:53

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 5 OCT 2020

---

Collection time (*00:00-23:59*) 13:51 (24 HR)

---

Collection date and time (derived) 5 OCT 2020 13:51

---

US3312008

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 21:37:46

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 14:18:12
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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

---

Date and time of submission

---

Patient Cloud Open Date & Time

17 OCT 2020 00:01

---

Patient Cloud Close Date & Time

21 OCT 2020 23:59

---

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 27 OCT 2020 12:58:42

Patient Cloud Open Date & Time 24 OCT 2020 00:01

Patient Cloud Close Date & Time 28 OCT 2020 23:59

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

---

Patient Cloud Close Date & Time

11 NOV 2020 23:59

---

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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"/>

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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

---

Date and time of submission

---

Patient Cloud Open Date & Time

14 NOV 2020 00:01

---

Patient Cloud Close Date & Time

18 NOV 2020 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 103

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

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2020 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 110

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2020 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2020 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

---

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

---

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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 16 DEC 2020 14:19:13

Patient Cloud Open Date & Time 16 DEC 2020 00:01

Patient Cloud Close Date & Time 20 DEC 2020 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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 <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 DEC 2020 15:21:08
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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 30 DEC 2020 15:48:52

Patient Cloud Open Date & Time 30 DEC 2020 00:01

Patient Cloud Close Date & Time 03 JAN 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 JAN 2021 04:05:23
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 16:53:34
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 20 JAN 2021 16:14:04

Patient Cloud Open Date & Time 20 JAN 2021 00:01

Patient Cloud Close Date & Time 24 JAN 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 27 JAN 2021 10:14:59

Patient Cloud Open Date & Time 27 JAN 2021 00:01

Patient Cloud Close Date & Time 31 JAN 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 08:33:22
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 10:53:50
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 17 FEB 2021 10:34:52

Patient Cloud Open Date & Time 17 FEB 2021 00:01

Patient Cloud Close Date & Time 21 FEB 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 24 FEB 2021 22:50:33

Patient Cloud Open Date & Time 24 FEB 2021 00:01

Patient Cloud Close Date & Time 28 FEB 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	03 MAR 2021 16:07:35
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 MAR 2021 15:15:31
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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 <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	17 MAR 2021 20:40:02
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 229

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

No

Yes

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

No

Yes

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

Date and time of submission 24 MAR 2021 12:13:36

Patient Cloud Open Date & Time 24 MAR 2021 00:01

Patient Cloud Close Date & Time 28 MAR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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 31 MAR 2021 11:47:28

Patient Cloud Open Date & Time 31 MAR 2021 00:01

Patient Cloud Close Date & Time 04 APR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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 <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	07 APR 2021 16:41:14
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 250

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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 22 APR 2021 17:23:31

Patient Cloud Open Date & Time 21 APR 2021 00:01

Patient Cloud Close Date & Time 25 APR 2021 23:59

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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  Yes

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 341

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 348

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 08 AUG 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 15 AUG 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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  Yes

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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   
Yes

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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  Yes

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 NOV 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 NOV 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 488

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 495

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 15 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 19 DEC 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JAN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#) 30 JAN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 FEB 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 FEB 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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  Yes

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 614

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 670

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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   
Yes

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

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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03 JUL 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 698

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUL 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 726

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#) 07 AUG 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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   
Yes

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

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

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

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 SEP 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

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US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59

---

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

DAY 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

---

US3312008

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:00:53

---

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
<a href="#">No</a>		<a href="#">11 MAR 2021 15:15:52</a>

---

US3312008

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:19:39

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 02 NOV 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3312008

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 7 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

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

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 01 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:19:55

Generated On: 09 Jun 2021 17:00:53

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 05 MAR 2021

---

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

---

Folder OID VISIT4

---

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 17:19:55

Generated On: 09 Jun 2021 17:00:53

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3312008

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 17:19:55

Generated On: 09 Jun 2021 17:00:53

---

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.*

---

US3312008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:19:55

Generated On: 09 Jun 2021 17:00:53

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 05 MAR 2021

---

Collection time (*00:00-23:59*) 13:22 (24 HR)

---

Collection date and time (derived) 05 MAR 2021 13:22

---

US3312008

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:19:55

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3312008

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 02 APR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3312008

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3312008**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:00:53**

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* \_\_\_\_\_

**US3312008**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:00:53**

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3312008

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:00:53

---

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"/>

---

**US3312008**

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

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

**Generated On: 09 Jun 2021 17:00:53**

---

Generate Next COVID-19 Assessment

Yes

No

---

US3312008

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 11 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3312008

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

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

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

Was the participant unblinded? Yes   
No

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

Date of unblinding (*dd MMM yyyy*) 11 JAN 2021

Participant randomization assignment mRNA-1273   
Placebo

Actual Dose 1 mRNA-1273   
Placebo   
Not Administered

Actual Dose 2 mRNA-1273   
Placebo   
Not Administered

Will participant receive mRNA-1273? Yes   
No

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

US3312008

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 JAN 2021

---

Collection time (*00:00-23:59*) 12:39 (24 HR)

---

Collection date and time (derived) 11 JAN 2021 12:39

---

US3312008

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 JAN 2021

---

Collection time (*00:00 - 23:59*) 12:38

---

Collection Date and Time (derived) 11 JAN 2021 12:38

---

US3312008

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 15:41:17

Generated On: 09 Jun 2021 17:00:53

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

AEID

Adverse event DOG BITE LEFT SHIN

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) 20 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) 30 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

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

AEID

Adverse event

FACIAL FRACTURES X3

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)

31 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)

02 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild

Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious?

Yes

No

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes

No

Unknown

Number of Days in ICU

PRODUCTION RELEASE (v12.003

354 of 2432

EAB) (1725)

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

AEID USA-US300-2021-MRNA-1273-P30  
1000024

Adverse event CORONARY ARTERY  
INSUFFICIENCY (INVOLVING  
THE LEFT ANTERIOR  
DESCENDING AND LEFT  
CIRCUMFLEX CORONARY  
ARTERIES)

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 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy)

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 True

Hospital Admission Date (dd MMM yyyy) 15 APR 2021

Hospital Discharge Date (dd MMM yyyy) 18 APR 2021

PRODUCTION RELEASE (v12.003 356 of 2432  
EAB) (1725)

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Admitted to ICU? Yes   
No   
Unknown

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   
Related   
Not Applicable

Relationship to Study Procedure Not Related   
Related   
Not Applicable

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative \_\_\_\_\_

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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SUBJ REPORTS  
HOSPITALIZATION FROM 15  
APR 2021 TO 18 APR 2021. ON  
ROUGHLY 25 MAR 2021,  
SUBJECT BEGAN  
EXPERIENCING DULL, ACHING,  
INTERMITTENT PAIN IN LEFT  
ARM, WHICH SHE PRESUMED  
TO BE RELATED TO HX OF  
LYMPHEDEMA SECONDARY TO  
MASTECTOMY. PAIN  
PERSISTED FOR SEVERAL  
WEEKS PROMPTING  
SCHEDULED PCP VISIT 15 APR  
2021 REPORTEDLY, PCP  
IDENTIFIED BP OF 198/90,  
ABNORMAL EKG, FOLLOWED  
BY IMMEDIATE REFERRAL TO  
LOCAL ED, SUBJECT WAS  
ADMITTED FOR NONINVASIVE  
CARDIAC WORKUP INVOLVING  
ECHO AND CHEMICAL STRESS  
TEST, REVEALING SUBACUTE  
MI. SHE WAS D/C'D ON 18 APR  
2021 WITH NEW RX FOR  
CARVEDILOL, HYDRALAZINE,  
ROSUVASTATIN, NORVASC,  
AND ASA. SUBJECT AWAITING  
OUTPATIENT CARDIAC REHAB  
AND F/U WITH CARDIOLOGIST  
ON 12 MAY 2021. PENDING  
RECEIPT OF MED RECS.  
UPDATE 30APR21: UPDATED  
SAE START DATE TO FEB2021,  
SUBJECT WAS ADMITTED FOR

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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UNSTABLE ANGINA AND  
BENIGN ESSENTIAL HTN.  
WORKUP REVEALED  
ELEVATED BNP, RALES, AND  
PERIPHERAL EDEMA. SUBJECT  
WAS DIAGNOSED WITH ACUTE  
DIASTOLIC CHF WITH  
PRESERVED EF, MI RULED OUT.  
MPI SHOWED REVERSIBLE  
ISCHEMIA IN LAD AND LEFT  
CIRCUMFLEX, PROMPTING  
RECOMMENDATION FOR LHC.  
SUBJECT ELECTED MEDICAL  
MANAGEMENT GIVEN HX OF  
CKD3 AND RIGHT  
NEPHRECTOMY. SHE WAS  
D/C'D ON 18 APR 2021 WITH  
NEW RX FOR CARVEDILOL,  
HYDRALAZINE,  
ROSUVASTATIN, NORVASC,  
AND ASA. SUBJECT AWAITING  
OUTPATIENT CARDIAC REHAB  
AND F/U WITH CARDIOLOGIST  
ON 12 MAY 2021.

---

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

---

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

AEID \_\_\_\_\_

Adverse event CONGESTIVE HEART FAILURE

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 FEB 2021

Start time (00:00-23:59) \_\_\_\_\_

AE start date and time (derived) \_\_\_\_\_

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) \_\_\_\_\_

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 \_\_\_\_\_

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

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

Yes

No

---

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

---

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication DILTIAZEM

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 120

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

363 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication METROPROLOL

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

365 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 25

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

367 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2010

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 31 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication FLUOXETINE

Prophylaxis Yes   
No

Indication ANXIETY

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

369 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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 1980

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication MAGNESIUM

Prophylaxis Yes   
No

Indication BILATERAL FOOT CRAMPS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

371 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication VITAMIN D

Prophylaxis Yes   
No

Indication HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

373 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2014

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes   
No

Indication GENERAL HEALTH MAINTENANCE

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

375 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

---

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) UN UNK 2014

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication DIFFICULTY SLEEPING

Dose per administration 325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

377 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN UNK 2015

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication HYDROCODONE/  
ACETAMINOPHEN

Prophylaxis Yes   
No

Indication FACIAL FRACTURES X3

Dose per administration 5/325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

379 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

---

	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) 31 DEC 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 07 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

---

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication CLINDAMYCIN

Prophylaxis Yes   
No

Indication FACIAL FRACTURES X3

Dose per administration 300

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

381 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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) 31 DEC 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 07 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication CULTURELLE PROBIOTICS  
(LACTOBACILLUS/INULIN)

Prophylaxis Yes   
No

Indication GASTROINTESTINAL HEALTH  
MAINTENANCE

Dose per administration 40/200

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

383 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

---

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)	31 DEC 2020
--------------------------	-------------

---

Start date completely unknown	False
-------------------------------	-------

---

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

If not Ongoing, End date (dd MMM yyyy)	07 JAN 2021
--	-------------

---

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"/>

---

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication TDAP (TETANUS DIPHTHERIA  
PERTUSSIS) BOOSTER VACCINE

Prophylaxis Yes   
No

Indication TETANUS PROPHYLAXIS

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

385 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

---

Intraocular	<input type="checkbox"/>
Intramuscular	<input checked="" type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) 21 DEC 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) 21 DEC 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication CLINDAMYCIN

Prophylaxis Yes   
No

Indication DOG BITE LEFT SHIN

Dose per administration 300

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

387 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify	
Start date (dd MMM yyyy)	21 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication CARVEDILOL

Prophylaxis Yes   
No

Indication CONGESTIVE HEART FAILURE

Dose per administration 6.25

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

389 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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) 18 APR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication HYDRALAZINE

Prophylaxis Yes   
No

Indication CONGESTIVE HEART FAILURE

Dose per administration 25

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

391 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

---

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*) 18 APR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication ROSUVASTATIN

Prophylaxis Yes   
No

Indication CORONARY ARTERY DISEASE

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

393 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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*) 18 APR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication NORVASC

Prophylaxis Yes   
No

Indication CONGESTIVE HEART FAILURE

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

395 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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) 18 APR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication CORONARY ARTERY DISEASE

Dose per administration 81

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

397 of 2432

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 30 Apr 2021 19:09:02

Generated On: 09 Jun 2021 17:00:53

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) 18 APR 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3312008

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 17:19:38

Generated On: 09 Jun 2021 17:00:53

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3312008

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:00:53

---

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

---

US3312008

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:00:53

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

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 20:48:52

Generated On: 09 Jun 2021 17:00:53

SAEID	USA-US300-2021-MRNA-1273-P301000024
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 20:48:52

Generated On: 09 Jun 2021 17:00:53

SAEID	USA-US300-2021-MRNA-1273-P30 1000024
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/APR/2021 08:21
<b>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.</b>	True

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 20:48:52

Generated On: 09 Jun 2021 17:00:53

SAEID	USA-US300-2021-MRNA-1273-P301000024
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	30/APR/2021 15:20
<b>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.</b>	True

Audit

US3312008 (Prod: Johnson County Clin-Trials)

**US3312008**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:00:53**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:57:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'US3312008'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:39:22

US3312008

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:49
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:01

US3312008

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:49
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:39:23

US3312008

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:49
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:01

US3312008

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'SCRN'	System	10 Aug 2020 18:56:01

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered (b) (6) 1933'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:39:23

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '86'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'YEARS'	System	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '87'	System	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered 'Female (F)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '1'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:00:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:55:00
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:26

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered '10 Aug 2020'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Aug 2020'	System	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2020'	System	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Aug 2020 21:17:19
User entered 'Amendment 1 (1)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:21

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:44
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 17:39:23

US3312008

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:00:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1'	System	10 Aug 2020 18:56:29

US3312008

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:52:02
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:29

US3312008

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:00:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:28
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:45:46

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 18:48:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 18:48:18
Data point term sent to Coder	System	11 Aug 2020 18:48:00
User entered 'hypercholesterolemia'	Kelly Moen (b) (4)	11 Aug 2020 18:47:03
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1990'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 18:47:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:47:18
User entered 'No (N)' reason for change: Data Entry Error	Kelly Moen (b) (4)	11 Aug 2020 18:47:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 18:47:03
User entered empty.	System	11 Aug 2020 18:47:03
	Kelly Moen (b) (4)	11 Aug 2020 18:47:03
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2015'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1990'	System	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1990'	System	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2015'	System	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2015'	System	11 Aug 2020 18:47:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 10:00:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 10:00:24
Data point term sent to Coder	System	11 Aug 2020 18:48:06
User entered 'allergy to beta blockers'	Kelly Moen (b) (4)	11 Aug 2020 18:48:03
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1980'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1980'	System	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1980'	System	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:48:03

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 18:50:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:50:17
Data point term sent to Coder	System	11 Aug 2020 18:49:09
User entered 'allergy to ace inhibitors'	Kelly Moen (b) (4)	11 Aug 2020 18:48:32
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1980'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1980'	System	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1980'	System	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:48:32

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:50:16
Data point term sent to Coder	System	11 Aug 2020 18:49:10
User entered 'penicillin allergy'	Kelly Moen (b) (4)	11 Aug 2020 18:49:07
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1960'	System	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:49:07

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Allergic reaction to bee sting - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:24:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:24:43
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Bee sting hypersensitivity - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:52:17
Data point term sent to Coder	System	11 Aug 2020 18:51:17
User entered 'bee sting allergy'	Kelly Moen (b) (4)	11 Aug 2020 18:51:10
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1985'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1985'	System	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1985'	System	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 18:51:10

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 18:53:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 18:53:16
Data point term sent to Coder	System	11 Aug 2020 18:52:18
User entered 'total hysterectomy'	Kelly Moen (b) (4)	11 Aug 2020 18:51:42
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1970'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 18:51:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 18:51:48
User entered 'No (N)' reason for change: Data Entry Error	Kelly Moen (b) (4)	11 Aug 2020 18:51:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 18:51:42
User entered empty.	System	11 Aug 2020 18:51:42
	Kelly Moen (b) (4)	11 Aug 2020 18:51:42
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1970'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1970'	System	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1970'	System	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1970'	System	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1970'	System	11 Aug 2020 18:51:42

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Nephrectomy, LLT: Nephrectomy - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 11:09:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 11:09:25
Data point term sent to Coder	System	11 Aug 2020 18:53:20
User entered 'right nephrectomy'	Kelly Moen (b) (4)	11 Aug 2020 18:52:39
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '04 Jul 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '04 Jul 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jul 1960'	System	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jul 1960'	System	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 18:52:39

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal disorders NEC, PT: Renal haematoma, LLT: Renal hematoma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	29 Sep 2020 10:49:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 10:49:51
Data point term sent to Coder	System	11 Aug 2020 18:54:23
User entered 'ruptured benign hematoma on right kidney'	Kelly Moen (b) (4)	11 Aug 2020 18:53:27
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '04 Jul 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '04 Jul 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jul 1960'	System	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jul 1960'	System	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 18:53:27

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Hepatobiliary disorders, HLT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 13:07:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 13:07:21
Data point term sent to Coder	System	11 Aug 2020 18:54:25
User entered 'cholethiasis'	Kelly Moen (b) (4)	11 Aug 2020 18:53:59
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2018'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2018'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2018'	System	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2018'	System	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2018'	System	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2018'	System	11 Aug 2020 18:53:59

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:56:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 18:56:15
Data point term sent to Coder	System	11 Aug 2020 18:55:28
User entered 'cholecystectomy'	Kelly Moen (b) (4)	11 Aug 2020 18:54:43
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2018'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2018'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2018'	System	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2018'	System	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2018'	System	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2018'	System	11 Aug 2020 18:54:43

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Spinal laminectomy - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 18:56:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 18:56:16
Data point term sent to Coder	System	11 Aug 2020 18:55:28
User entered 'laminectomy'	Kelly Moen (b) (4)	11 Aug 2020 18:55:08
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2005'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2005'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2005'	System	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2005'	System	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2005'	System	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2005'	System	11 Aug 2020 18:55:08

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Ruptured intervertebral disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:52:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:52:42
Data point term sent to Coder	System	11 Aug 2020 18:56:30
User entered 'ruptured disc'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2005'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2005'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2005'	System	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2005'	System	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2005'	System	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2005'	System	11 Aug 2020 18:55:36

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Spinal compression fracture, LLT: Spinal compression fracture - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:06:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 22:06:12
Data point term sent to Coder	System	11 Aug 2020 18:56:30
User entered 'back compression fracture'	Kelly Moen (b) (4)	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2015'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2015'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2015'	System	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2015'	System	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2015'	System	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2015'	System	11 Aug 2020 18:56:17

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:04:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:04:18
Data point term sent to Coder	System	11 Aug 2020 19:02:44
User entered 'endometriosis'	Kelly Moen (b) (4)	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1970'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1970'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1970'	System	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1970'	System	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1970'	System	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1970'	System	11 Aug 2020 19:02:11

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 19:04:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:04:19
Data point term sent to Coder	System	11 Aug 2020 19:03:47
User entered 'left hip replacement'	Kelly Moen (b) (4)	11 Aug 2020 19:03:07
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2012'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2012'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2012'	System	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2012'	System	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2012'	System	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2012'	System	11 Aug 2020 19:03:07

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:04:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 19:03:47
User entered 'right hip replacement'	Kelly Moen (b) (4)	11 Aug 2020 19:03:32
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2015'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Oct 2015'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2015'	System	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2015'	System	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Oct 2015'	System	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2015'	System	11 Aug 2020 19:03:32

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 14:01:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 14:01:45
Data point term sent to Coder	System	11 Aug 2020 19:04:49
User entered 'osteoporosis bilateral hips'	Kelly Moen (b) (4)	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Jan 2012'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Jan 2012'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2012'	System	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2012'	System	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2012'	System	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2012'	System	11 Aug 2020 19:04:07

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:06:14
Data point term sent to Coder	(b) (4)	
User entered 'hypertension'	System	11 Aug 2020 19:04:49
	Kelly Moen (b) (4)	11 Aug 2020 19:04:24
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1990'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1990'	System	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1990'	System	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:04:24

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:06:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:06:13
Data point term sent to Coder	System	11 Aug 2020 19:04:50
User entered 'anxiety'	Kelly Moen (b) (4)	11 Aug 2020 19:04:47
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1980'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:46
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 19:11:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:11:37
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 19:04:47
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1980'	System	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1980'	System	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:04:47

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 11:24:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 11:24:21
Data point term sent to Coder	System	11 Aug 2020 19:05:50
User entered 'left total mastectomy'	Kelly Moen (b) (4)	11 Aug 2020 19:05:21
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '13 Mar 1996'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '13 Mar 1996'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Mar 1996'	System	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1996'	System	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Mar 1996'	System	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1996'	System	11 Aug 2020 19:05:21

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 19:08:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:08:18
Data point term sent to Coder	System	11 Aug 2020 19:06:52
User entered 'left breast cancer'	Kelly Moen (b) (4)	11 Aug 2020 19:06:02
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Dec 1995'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '13 Mar 1996'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Dec 1995'	System	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1995'	System	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Mar 1996'	System	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1996'	System	11 Aug 2020 19:06:02

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Vascular disorders, HLGT: Lymphatic vessel disorders, HLT: Lymphoedemas, PT: Lymphoedema, LLT: Lymphedema - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 08:39:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 08:39:13
Data point term sent to Coder	System	11 Aug 2020 19:08:54
User entered 'left arm lymphedema'	Kelly Moen (b) (4)	11 Aug 2020 19:08:21
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un Sep 1997'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Sep 1997'	System	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1997'	System	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:08:21

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Hay fever - 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)	11 Aug 2020 19:11:19
Data point term sent to Coder	(b) (4)	
User entered 'hay fever'	System	11 Aug 2020 19:09:56
	Kelly Moen (b) (4)	11 Aug 2020 19:09:03
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1958'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1958'	System	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1958'	System	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 1960'	System	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 19:09:03

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:11:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 19:11:19
Data point term sent to Coder	System	11 Aug 2020 19:09:58
User entered 'appendectomy'	Kelly Moen (b) (4)	11 Aug 2020 19:09:50
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '04 Jul 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '04 Jul 1960'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jul 1960'	System	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jul 1960'	System	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1960'	System	11 Aug 2020 19:09:50

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Foot cramps - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 11:27:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 11:27:21
Data point term sent to Coder	System	11 Aug 2020 19:10:59
User entered 'bilateral foot cramps'	Kelly Moen (b) (4)	11 Aug 2020 19:10:35
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2019'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	15 Feb 2021 21:37:46
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 19:10:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:10:44
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 19:10:35
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2019'	System	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2019'	System	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:10:35

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Difficulty sleeping - 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)	11 Aug 2020 19:12:21
Data point term sent to Coder	(b) (4)	
User entered 'difficulty sleeping'	System	11 Aug 2020 19:12:00
	Kelly Moen (b) (4)	11 Aug 2020 19:11:06
	(b) (4)	

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'un UNK 2015'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:46:28
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'Jan 2015'	System	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '2015'	System	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	11 Aug 2020 19:11:06

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered '12:15'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '10 Aug 2020 12:15'	System	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered '61.0' in	Kelly Moen (b) (4)	11 Aug 2020 19:12:59
DataPoint set to visible.	(b) (4) System	10 Aug 2020 18:56:29

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered '154.8' lb	Kelly Moen (b) (4)	11 Aug 2020 19:12:59
DataPoint set to visible.	(b) (4) System	10 Aug 2020 18:56:29

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
Amendment Manager: User entered '29.31036'	System	16 Sep 2020 23:50:14
User entered '29.3'	System	11 Aug 2020 19:12:59
DataPoint set to visible.	System	10 Aug 2020 18:56:29

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'kg/m2'	System	11 Aug 2020 19:12:59
DataPoint set to visible.	System	10 Aug 2020 18:56:29

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'bpm'	System	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'breaths/min'	System	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'mmHg'	System	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:21:48
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'mmHg'	System	11 Aug 2020 19:12:59

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56

US3312008

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56

US3312008

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:22:10
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:13:12

US3312008

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:22:10
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 09:55:33
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		07 Sep 2020 18:51:20
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:13:12

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered 'Surgically sterile (SURGICALLY STERILE)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered 'un UNK 1970'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:00:53

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:51:36
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:16:49

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Manufacturing & Production Operations](#) with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Border Protection and Military Personnel](#) (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '0'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered '1'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered '1'	(b) (4) Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:00:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:50:09
User entered 'resides in community with ongoing person to person transmission'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:18:42

US3312008

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:13
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:47

US3312008

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:13
User entered '10 Aug 2020'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:47

US3312008

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:13
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:56:47

US3312008

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'VISIT1'	System	10 Aug 2020 18:56:47

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 18:29:51

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:23
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:20:31
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:20:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 18:29:51
User entered '185427' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 18:29:51

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 18:29:51

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

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)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:05

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

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)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:05

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:05

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:05

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:21
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:05

US3312008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:00:53

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:41:01
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
User entered 'No (N)'	(b) (4) Heather Barker (b) (4)	30 Oct 2020 17:10:08
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:04:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:49:03

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '12:15'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '10 Aug 2020 12:15'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '98.1' F	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '53'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'bpm'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '16'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'breaths/min'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:25
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Un-verified.	(b) (4) Monica Atwood (b) (4)	28 Jan 2021 00:56:39
User entered '163' reason for change: Data Entry Error	(b) (4) Monica Atwood (b) (4)	28 Jan 2021 00:56:39
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:24:33
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:31:29
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 'Correct as entered. NCS. See unscheduled repeat vitals.' (Site from System).	Karol Moore (b) (4) (b) (4)	13 Aug 2020 18:22:08
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 19:27:08
User entered '169'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '81'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:00:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered missing code ND - Not Done.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 07:04:07
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 19:27:08
User entered '14:18'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '10 Aug 2020 14:18'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '97.9' F	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered 'Oral (Oral)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '57'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'bpm'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '16'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'breaths/min'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 15:31:31
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 'Correct as entered. NCS. See unscheduled repeat vitals.' (Site from System).	Karol Moore (b) (4) (b) (4)	13 Aug 2020 18:22:14
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 19:27:08
User entered '159'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:24:33
User entered '62'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Aug 2020 19:27:08

US3312008

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:12
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:56

US3312008

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:12
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:27:56

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

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)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered empty.	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered '10 Aug 2020'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered '13:47'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '10 Aug 2020 13:47'	System	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered 'Right Arm (RIGHT ARM)'	Christa Estrada (b) (4) (b) (4)	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:23:56
User entered 'ONCE'	System	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 18:57:49

US3312008

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:34
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:30:46

US3312008

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:34
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:30:46

US3312008

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:34
User entered '13:16'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:30:46

US3312008

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '10 Aug 2020 13:16'	System	11 Aug 2020 19:30:46

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:39
User entered '10 Aug 2020'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:22

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:22

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:39
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:22

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:39
User entered '12:47'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:22

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '10 Aug 2020 12:47'	System	11 Aug 2020 19:31:22

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:26

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:39
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:26

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:23:39
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:26

US3312008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered empty.	System	11 Aug 2020 19:31:26

US3312008

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:27:17
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:31:36

US3312008

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	11 Aug 2020 19:31:36

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:17:16', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2e9c3e0-7573-4f44-a776-f0e94f15b02a' User entered 'Yes (Y)'	System	10 Aug 2020 19:18:02
	System	10 Aug 2020 19:18:02

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:17:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2e9c3e0-7573-4f44-a776-f0e94f15b02a' User entered '97.9'	System	10 Aug 2020 19:18:02
	System	10 Aug 2020 19:18:02

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:17:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2e9c3e0-7573-4f44-a776-f0e94f15b02a'	System	10 Aug 2020 19:18:02
User entered 'No (N)'	System	10 Aug 2020 19:18:02

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:17:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2e9c3e0-7573-4f44-a776-f0e94f15b02a' User entered '10 Aug 2020 14:17'	System	10 Aug 2020 19:18:02
	System	10 Aug 2020 19:18:02

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 14:07'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ac9848a8-8d38-476c-a4e6-37a68296abd' User entered 'Yes (Y)'	System	11 Aug 2020 00:54:16
	System	11 Aug 2020 00:54:16

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:53:59', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ac9848a8-8d38-476c-a4e6-37a68296abd' User entered '97.7'	System	11 Aug 2020 00:54:16
	System	11 Aug 2020 00:54:16

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ac9848a8-8d38-476c-a4e6-37a68296abd' User entered 'No (N)'	System	11 Aug 2020 00:54:16
	System	11 Aug 2020 00:54:16

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ac9848a8-8d38-476c-a4e6-37a68296abd' User entered '10 Aug 2020 19:54'	System	11 Aug 2020 00:54:16
	System	11 Aug 2020 00:54:16

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 17:32'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 2'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:20', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a7e0d663-af4f-49ce-9cc5-fd177de55f82'	System	11 Aug 2020 23:19:43
User entered 'Yes (Y)'	System	11 Aug 2020 23:19:43

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:29', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a7e0d663-af4f-49ce-9cc5-fd177de55f82'	System	11 Aug 2020 23:19:43
User entered '97.8'	System	11 Aug 2020 23:19:43

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a7e0d663-af4f-49ce-9cc5-fd177de55f82'	System	11 Aug 2020 23:19:43
User entered 'No (N)'	System	11 Aug 2020 23:19:43

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:40', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a7e0d663-af4f-49ce-9cc5-fd177de55f82'	System	11 Aug 2020 23:19:43
User entered '11 Aug 2020 18:19'	System	11 Aug 2020 23:19:43

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 3'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:44:45', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22b73cc9-cc35-4264-b88f-42c61849af8d' User entered 'Yes (Y)'	System	13 Aug 2020 01:45:13
	System	13 Aug 2020 01:45:13

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:44:56', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22b73cc9-cc35-4264-b88f-42c61849af8d' User entered '98.6'	System	13 Aug 2020 01:45:13
	System	13 Aug 2020 01:45:13

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:01', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22b73cc9-cc35-4264-b88f-42c61849af8d'	System	13 Aug 2020 01:45:13
User entered 'No (N)'	System	13 Aug 2020 01:45:13

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:10', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22b73cc9-cc35-4264-b88f-42c61849af8d' User entered '12 Aug 2020 20:45'	System	13 Aug 2020 01:45:13
	System	13 Aug 2020 01:45:13

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 4'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:12:39', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3d1c1ca6-238a-4d21-a596-044d5bbd82c2' User entered 'Yes (Y)'	System	13 Aug 2020 21:12:51
	System	13 Aug 2020 21:12:51

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:12:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3d1c1ca6-238a-4d21-a596-044d5bbd82c2' User entered '96.7'	System	13 Aug 2020 21:12:51
	System	13 Aug 2020 21:12:51

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:12:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3d1c1ca6-238a-4d21-a596-044d5bbd82c2'	System	13 Aug 2020 21:12:51
User entered 'No (N)'	System	13 Aug 2020 21:12:51

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:12:45', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3d1c1ca6-238a-4d21-a596-044d5bbd82c2' User entered '13 Aug 2020 16:12'	System	13 Aug 2020 21:12:51
	System	13 Aug 2020 21:12:51

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 5'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:13:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22c6d32c-d75b-40c4-9bc5-9eb9b1428354' User entered 'Yes (Y)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:05', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22c6d32c-d75b-40c4-9bc5-9eb9b1428354' User entered '97.6'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:10', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22c6d32c-d75b-40c4-9bc5-9eb9b1428354'	System	14 Aug 2020 20:15:15
User entered 'No (N)'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:17', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '22c6d32c-d75b-40c4-9bc5-9eb9b1428354'	System	14 Aug 2020 20:15:15
User entered '14 Aug 2020 15:14'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 6'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:24', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5eafa0fe-1851-4785-a487-d56345eae898'	System	15 Aug 2020 20:44:41
User entered 'Yes (Y)'	System	15 Aug 2020 20:44:41

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:31', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5eafa0fe-1851-4785-a487-d56345eae898' User entered '97.6'	System	15 Aug 2020 20:44:41
	System	15 Aug 2020 20:44:41

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:34', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5eafa0fe-1851-4785-a487-d56345eae898'	System	15 Aug 2020 20:44:41
User entered 'No (N)'	System	15 Aug 2020 20:44:41

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5eafa0fe-1851-4785-a487-d56345eae898'	System	15 Aug 2020 20:44:41
User entered '15 Aug 2020 15:44'	System	15 Aug 2020 20:44:41

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 7'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:39:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e44a3727-1a34-4487-887f-9a326a6dc7b0'	System	16 Aug 2020 21:39:53
User entered 'Yes (Y)'	System	16 Aug 2020 21:39:53

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:39:35', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e44a3727-1a34-4487-887f-9a326a6dc7b0'	System	16 Aug 2020 21:39:53
User entered '97.6'	System	16 Aug 2020 21:39:53

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:39:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e44a3727-1a34-4487-887f-9a326a6dc7b0'	System	16 Aug 2020 21:39:53
User entered 'No (N)'	System	16 Aug 2020 21:39:53

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:39:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e44a3727-1a34-4487-887f-9a326a6dc7b0'	System	16 Aug 2020 21:39:53
User entered '16 Aug 2020 16:39'	System	16 Aug 2020 21:39:53

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:18:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6fa488d4-9bc7-410f-a504-c7bfe77a4501'	System	10 Aug 2020 19:19:01
User entered 'None (1)'	System	10 Aug 2020 19:19:01

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:18:37', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6fa488d4-9bc7-410f-a504-c7bfe77a4501'	System	10 Aug 2020 19:19:01
User entered 'No (N)'	System	10 Aug 2020 19:19:01

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:18:41', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6fa488d4-9bc7-410f-a504-c7bfe77a4501'	System	10 Aug 2020 19:19:01
User entered 'No (N)'	System	10 Aug 2020 19:19:01

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:18:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6fa488d4-9bc7-410f-a504-c7bfe77a4501'	System	10 Aug 2020 19:19:01
User entered 'None (1)'	System	10 Aug 2020 19:19:01

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:18:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6fa488d4-9bc7-410f-a504-c7bfe77a4501' User entered '10 Aug 2020 14:18'	System	10 Aug 2020 19:19:01
	System	10 Aug 2020 19:19:01

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 14:07'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:19', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '28754a46-b55c-481d-a230-ec1b439116b9'	System	11 Aug 2020 00:54:38
User entered 'None (1)'	System	11 Aug 2020 00:54:38

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:23', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '28754a46-b55c-481d-a230-ec1b439116b9'	System	11 Aug 2020 00:54:38
User entered 'No (N)'	System	11 Aug 2020 00:54:38

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:26', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '28754a46-b55c-481d-a230-ec1b439116b9'	System	11 Aug 2020 00:54:38
User entered 'No (N)'	System	11 Aug 2020 00:54:38

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:30', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '28754a46-b55c-481d-a230-ec1b439116b9'	System	11 Aug 2020 00:54:38
User entered 'None (1)'	System	11 Aug 2020 00:54:38

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:34', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '28754a46-b55c-481d-a230-ec1b439116b9' User entered '10 Aug 2020 19:54'	System	11 Aug 2020 00:54:38
	System	11 Aug 2020 00:54:38

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 17:32'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 2'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:47', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c6a7c5c6-ed92-4b55-b458-26d351e5f2c4'	System	11 Aug 2020 23:20:03
User entered 'None (1)'	System	11 Aug 2020 23:20:03

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:50', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c6a7c5c6-ed92-4b55-b458-26d351e5f2c4' User entered 'No (N)'	System	11 Aug 2020 23:20:03
	System	11 Aug 2020 23:20:03

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:53', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c6a7c5c6-ed92-4b55-b458-26d351e5f2c4' User entered 'No (N)'	System	11 Aug 2020 23:20:03
	System	11 Aug 2020 23:20:03

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:56', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c6a7c5c6-ed92-4b55-b458-26d351e5f2c4'	System	11 Aug 2020 23:20:03
User entered 'None (1)'	System	11 Aug 2020 23:20:03

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:19:59', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c6a7c5c6-ed92-4b55-b458-26d351e5f2c4' User entered '11 Aug 2020 18:19'	System	11 Aug 2020 23:20:03
	System	11 Aug 2020 23:20:03

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 3'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:15', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dbdff897-0899-44be-892d-878dcf505e22'	System	13 Aug 2020 01:45:35
User entered 'None (1)'	System	13 Aug 2020 01:45:35

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:19', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dbdff897-0899-44be-892d-878dcf505e22'	System	13 Aug 2020 01:45:35
User entered 'No (N)'	System	13 Aug 2020 01:45:35

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:22', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dbdff897-0899-44be-892d-878dcf505e22'	System	13 Aug 2020 01:45:35
User entered 'No (N)'	System	13 Aug 2020 01:45:35

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:26', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dbdff897-0899-44be-892d-878dcf505e22'	System	13 Aug 2020 01:45:35
User entered 'None (1)'	System	13 Aug 2020 01:45:35

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:30', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dbdff897-0899-44be-892d-878dcf505e22'	System	13 Aug 2020 01:45:35
User entered '12 Aug 2020 20:45'	System	13 Aug 2020 01:45:35

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 4'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:12:54', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '615c8e75-3e6e-4b79-9dc1-07b3ee19cad3'	System	13 Aug 2020 21:13:13
User entered 'None (1)'	System	13 Aug 2020 21:13:13

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:12:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '615c8e75-3e6e-4b79-9dc1-07b3ee19cad3' User entered 'No (N)'	System	13 Aug 2020 21:13:13
	System	13 Aug 2020 21:13:13

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '615c8e75-3e6e-4b79-9dc1-07b3ee19cad3' User entered 'No (N)'	System	13 Aug 2020 21:13:13
	System	13 Aug 2020 21:13:13

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:05', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '615c8e75-3e6e-4b79-9dc1-07b3ee19cad3'	System	13 Aug 2020 21:13:13
User entered 'None (1)'	System	13 Aug 2020 21:13:13

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '615c8e75-3e6e-4b79-9dc1-07b3ee19cad3' User entered '13 Aug 2020 16:13'	System	13 Aug 2020 21:13:13
	System	13 Aug 2020 21:13:13

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 5'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:23', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '057d2d51-7931-488e-b0ac-4415f4e3b67d'	System	14 Aug 2020 20:15:15
User entered 'None (1)'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:26', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '057d2d51-7931-488e-b0ac-4415f4e3b67d' User entered 'No (N)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:29', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '057d2d51-7931-488e-b0ac-4415f4e3b67d' User entered 'No (N)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:32', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '057d2d51-7931-488e-b0ac-4415f4e3b67d' User entered 'None (1)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '057d2d51-7931-488e-b0ac-4415f4e3b67d' User entered '14 Aug 2020 15:14'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 6'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:42', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '75d6385e-fb3e-4aea-aead-ea344140bda6'	System	15 Aug 2020 20:44:58
User entered 'None (1)'	System	15 Aug 2020 20:44:58

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:45', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '75d6385e-fb3e-4aea-aead-ea344140bda6'	System	15 Aug 2020 20:44:58
User entered 'No (N)'	System	15 Aug 2020 20:44:58

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:49', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '75d6385e-fb3e-4aea-aead-ea344140bda6' User entered 'No (N)'	System	15 Aug 2020 20:44:58
	System	15 Aug 2020 20:44:58

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '75d6385e-fb3e-4aea-aead-ea344140bda6'	System	15 Aug 2020 20:44:58
User entered 'None (1)'	System	15 Aug 2020 20:44:58

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:54', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '75d6385e-fb3e-4aea-aead-ea344140bda6' User entered '15 Aug 2020 15:44'	System	15 Aug 2020 20:44:58
	System	15 Aug 2020 20:44:58

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 7'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:39:55', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6a170d71-9050-40cc-b88b-412d5c142a89'	System	16 Aug 2020 21:40:11
User entered 'None (1)'	System	16 Aug 2020 21:40:11

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6a170d71-9050-40cc-b88b-412d5c142a89'	System	16 Aug 2020 21:40:11
User entered 'No (N)'	System	16 Aug 2020 21:40:11

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:04', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6a170d71-9050-40cc-b88b-412d5c142a89'	System	16 Aug 2020 21:40:11
User entered 'No (N)'	System	16 Aug 2020 21:40:11

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:07', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6a170d71-9050-40cc-b88b-412d5c142a89'	System	16 Aug 2020 21:40:11
User entered 'None (1)'	System	16 Aug 2020 21:40:11

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:09', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '6a170d71-9050-40cc-b88b-412d5c142a89'	System	16 Aug 2020 21:40:11
User entered '16 Aug 2020 16:40'	System	16 Aug 2020 21:40:11

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:07', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee'	System	10 Aug 2020 19:19:50
User entered 'None (0)'	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:10', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered 'None (0)'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:14', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered 'None (0)'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered 'None (0)'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:34', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered 'None (0)'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:40', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered 'None (0)'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:43', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered 'No (N)'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T14:19:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ff02ad22-5860-41ce-a844-ac6322de5bee' User entered '10 Aug 2020 14:19'	System	10 Aug 2020 19:19:50
	System	10 Aug 2020 19:19:50

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 14:07'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:40', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered 'None (0)'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:43', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered 'None (0)'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d'	System	11 Aug 2020 00:55:01
User entered 'None (0)'	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered 'None (0)'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered 'None (0)'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:53', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered 'None (0)'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:55', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered 'No (N)'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-10T19:54:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cc25a8f0-9803-4fb4-8dc4-88ed4a4c3d2d' User entered '10 Aug 2020 19:54'	System	11 Aug 2020 00:55:01
	System	11 Aug 2020 00:55:01

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Aug 2020 17:32'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 2'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:07', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'None (0)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:09', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'None (0)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:11', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'None (0)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'None (0)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:16', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'None (0)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'None (0)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered 'No (N)'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-11T18:20:24', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '06f5e33e-2fed-4f97-8d0e-79e776c023fd' User entered '11 Aug 2020 18:20'	System	11 Aug 2020 23:20:28
	System	11 Aug 2020 23:20:28

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 3'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'None (0)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:39', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'None (0)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:42', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'None (0)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:45', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'None (0)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:49', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'None (0)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:54', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'None (0)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:45:57', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered 'No (N)'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-12T20:46:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3ef39aff-ed32-4ee7-8ed6-a82a4b7053c0' User entered '12 Aug 2020 20:46'	System	13 Aug 2020 01:46:03
	System	13 Aug 2020 01:46:03

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 4'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:17', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered 'None (0)'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:19', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered 'None (0)'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered 'None (0)'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:24', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered 'None (0)'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:26', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered 'None (0)'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered 'None (0)'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa'	System	13 Aug 2020 21:13:45
User entered 'No (N)'	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-13T16:13:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '870ce981-fc7c-4776-8655-6087c6ff01aa' User entered '13 Aug 2020 16:13'	System	13 Aug 2020 21:13:45
	System	13 Aug 2020 21:13:45

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 5'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:42', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b'	System	14 Aug 2020 20:15:15
User entered 'None (0)'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:44', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b'	System	14 Aug 2020 20:15:15
User entered 'None (0)'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b' User entered 'None (0)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b' User entered 'None (0)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b' User entered 'None (0)'	System	14 Aug 2020 20:15:15
	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:53', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b'	System	14 Aug 2020 20:15:15
User entered 'None (0)'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:56', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b'	System	14 Aug 2020 20:15:15
User entered 'No (N)'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-14T15:14:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'edc5e37e-6efc-4a70-afa0-e425be3c2f5b'	System	14 Aug 2020 20:15:15
User entered '14 Aug 2020 15:14'	System	14 Aug 2020 20:15:15

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

**US3312008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:00:53**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 6'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:44:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered 'None (0)'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963' User entered 'None (0)'	System	15 Aug 2020 20:45:17
	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered 'None (0)'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:05', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered 'None (0)'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered 'None (0)'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:10', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered 'None (0)'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered 'No (N)'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-15T15:45:15', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'eb35bd10-8bd6-4606-82af-f5faaa2bf963'	System	15 Aug 2020 20:45:17
User entered '15 Aug 2020 15:45'	System	15 Aug 2020 20:45:17

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 7'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0'	System	16 Aug 2020 21:40:35
User entered 'None (0)'	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:15', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0'	System	16 Aug 2020 21:40:35
User entered 'None (0)'	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0' User entered 'None (0)'	System	16 Aug 2020 21:40:35
	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:20', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0' User entered 'None (0)'	System	16 Aug 2020 21:40:35
	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:22', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0'	System	16 Aug 2020 21:40:35
User entered 'None (0)'	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:25', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0'	System	16 Aug 2020 21:40:35
User entered 'None (0)'	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0'	System	16 Aug 2020 21:40:35
User entered 'No (N)'	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-08-16T16:40:30', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '593eea05-3bab-4201-ab0f-564b0bfadfd0' User entered '16 Aug 2020 16:40'	System	16 Aug 2020 21:40:35
	System	16 Aug 2020 21:40:35

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 18:57:49

US3312008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:55
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:25:32

US3312008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:55
User entered '17 Aug 2020'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:25:32

US3312008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:55
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:25:32

US3312008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:55
User entered empty.	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:25:32

US3312008

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:20:53
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	17 Aug 2020 18:25:38

US3312008

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	17 Aug 2020 18:25:38

US3312008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:24
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:12:53

US3312008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:24
User entered '24 Aug 2020'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:12:53

US3312008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:24
User entered 'Contact Made (CONTACT MADE)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:12:53

US3312008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:24
User entered empty.	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:12:53

US3312008

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:34
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	24 Aug 2020 20:12:58

US3312008

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	24 Aug 2020 20:12:58

US3312008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:37
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 15:03:45

US3312008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:37
User entered '1 Sep 2020'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 15:03:45

US3312008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:37
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 15:03:45

US3312008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:37
User entered empty.	Karol Moore (b) (4) (b) (4)	02 Sep 2020 15:03:45

US3312008

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:28:40
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	02 Sep 2020 15:03:48

US3312008

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '1'	System	02 Sep 2020 15:03:48

US3312008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:29:14
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:20

US3312008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:29:14
User entered '7 Sep 2020'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:20

US3312008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:29:14
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:20

US3312008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'VISIT2'	System	07 Sep 2020 18:51:20

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '12:57'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '07 Sep 2020 12:57'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '65'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'bpm'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '12'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'breaths/min'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '123'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '67'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '14:19'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '07 Sep 2020 14:19'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '98.7' F	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '56'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'bpm'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '16'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'breaths/min'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '140'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:56
User entered '80'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	11 Sep 2020 15:34:42

US3312008

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:29:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:48

US3312008

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:29:57
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:34:48

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered empty.	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

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)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered empty.	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'MRNA-1273 OR PLACEBO'	System	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered '7 Sep 2020'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered '13:48'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '7 Sep 2020 13:48'	System	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered 'Right Arm (RIGHT ARM)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:30:21
User entered 'ONCE'	System	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:00:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'INTRAMUSCULAR'	System	07 Sep 2020 18:51:37

US3312008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:06
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:03

US3312008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:06
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:03

US3312008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:06
User entered '13:15'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:03

US3312008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '07 Sep 2020 13:15'	System	11 Sep 2020 15:35:03

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:10
User entered '07 Sep 2020'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:10
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:10
User entered '13:09'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '07 Sep 2020 13:09'	System	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:10
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:30:10
User entered empty.	Karol Moore (b) (4) (b) (4)	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:00:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered empty.	System	11 Sep 2020 15:35:15

US3312008

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:31:26
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	07 Sep 2020 18:51:43

US3312008

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '1'	System	07 Sep 2020 18:51:43

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:17:24', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e7cc68db-6212-41e3-aafa-8eabbfcea030'	System	07 Sep 2020 20:17:54
User entered 'Yes (Y)'	System	07 Sep 2020 20:17:54

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:17:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e7cc68db-6212-41e3-aafa-8eabbfcea030' User entered '98.1'	System	07 Sep 2020 20:17:54
	System	07 Sep 2020 20:17:54

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:17:42', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e7cc68db-6212-41e3-aafa-8eabbfcea030'	System	07 Sep 2020 20:17:54
User entered 'No (N)'	System	07 Sep 2020 20:17:54

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:17:53', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e7cc68db-6212-41e3-aafa-8eabbfcea030' User entered '07 Sep 2020 15:17'	System	07 Sep 2020 20:17:54
	System	07 Sep 2020 20:17:54

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 14:08'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 16:38'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:12:31', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd81e951b-103f-4311-a628-3e00ce5ba3d6' User entered 'Yes (Y)'	System	07 Sep 2020 23:12:55
	System	07 Sep 2020 23:12:55

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:12:43', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd81e951b-103f-4311-a628-3e00ce5ba3d6' User entered '98.1'	System	07 Sep 2020 23:12:55
	System	07 Sep 2020 23:12:55

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:12:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd81e951b-103f-4311-a628-3e00ce5ba3d6'	System	07 Sep 2020 23:12:55
User entered 'No (N)'	System	07 Sep 2020 23:12:55

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:12:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd81e951b-103f-4311-a628-3e00ce5ba3d6' User entered '07 Sep 2020 18:12'	System	07 Sep 2020 23:12:55
	System	07 Sep 2020 23:12:55

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 17:33'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 2'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:42:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '30a98f78-8c19-41eb-acaa-492e38894101' User entered 'Yes (Y)'	System	08 Sep 2020 22:42:21
	System	08 Sep 2020 22:42:21

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:42:10', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '30a98f78-8c19-41eb-acaa-492e38894101' User entered '98.1'	System	08 Sep 2020 22:42:21
	System	08 Sep 2020 22:42:21

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:42:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '30a98f78-8c19-41eb-acaa-492e38894101'	System	08 Sep 2020 22:42:21
User entered 'No (N)'	System	08 Sep 2020 22:42:21

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:42:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '30a98f78-8c19-41eb-acaa-492e38894101'	System	08 Sep 2020 22:42:21
User entered '08 Sep 2020 17:42'	System	08 Sep 2020 22:42:21

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 3'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:15:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '1bd8aa98-a9e5-4652-9662-59a92e5ab987' User entered 'Yes (Y)'	System	09 Sep 2020 21:15:18
	System	09 Sep 2020 21:15:18

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:15:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '1bd8aa98-a9e5-4652-9662-59a92e5ab987' User entered '98.1'	System	09 Sep 2020 21:15:18
	System	09 Sep 2020 21:15:18

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:15:11', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '1bd8aa98-a9e5-4652-9662-59a92e5ab987'	System	09 Sep 2020 21:15:18
User entered 'No (N)'	System	09 Sep 2020 21:15:18

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:15:15', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '1bd8aa98-a9e5-4652-9662-59a92e5ab987'	System	09 Sep 2020 21:15:18
User entered '09 Sep 2020 16:15'	System	09 Sep 2020 21:15:18

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 4'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:30', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '8e503a94-92c7-40f9-94f7-5f816dc5442f' User entered 'Yes (Y)'	System	10 Sep 2020 21:53:47
	System	10 Sep 2020 21:53:47

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '8e503a94-92c7-40f9-94f7-5f816dc5442f' User entered '98.2'	System	10 Sep 2020 21:53:47
	System	10 Sep 2020 21:53:47

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:40', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '8e503a94-92c7-40f9-94f7-5f816dc5442f' User entered 'No (N)'	System	10 Sep 2020 21:53:47
	System	10 Sep 2020 21:53:47

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:44', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '8e503a94-92c7-40f9-94f7-5f816dc5442f' User entered '10 Sep 2020 16:53'	System	10 Sep 2020 21:53:47
	System	10 Sep 2020 21:53:47

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 5'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:55:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a9d30210-8c19-46ab-9784-bdac648685cb' User entered 'Yes (Y)'	System	11 Sep 2020 21:56:17
	System	11 Sep 2020 21:56:17

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:55:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a9d30210-8c19-46ab-9784-bdac648685cb' User entered '98.1'	System	11 Sep 2020 21:56:17
	System	11 Sep 2020 21:56:17

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:55:49', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a9d30210-8c19-46ab-9784-bdac648685cb' User entered 'No (N)'	System	11 Sep 2020 21:56:17
	System	11 Sep 2020 21:56:17

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:55:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'a9d30210-8c19-46ab-9784-bdac648685cb' User entered '11 Sep 2020 16:55'	System	11 Sep 2020 21:56:17
	System	11 Sep 2020 21:56:17

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 6'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:20:54', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7c0534fd-6238-4138-ab1e-7336d4f66eda' User entered 'Yes (Y)'	System	13 Sep 2020 00:21:24
	System	13 Sep 2020 00:21:24

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:05', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7c0534fd-6238-4138-ab1e-7336d4f66eda' User entered '98.1'	System	13 Sep 2020 00:21:24
	System	13 Sep 2020 00:21:24

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7c0534fd-6238-4138-ab1e-7336d4f66eda' User entered 'No (N)'	System	13 Sep 2020 00:21:24
	System	13 Sep 2020 00:21:24

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:20', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7c0534fd-6238-4138-ab1e-7336d4f66eda' User entered '12 Sep 2020 19:21'	System	13 Sep 2020 00:21:24
	System	13 Sep 2020 00:21:24

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 7'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:01', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f12f5856-f937-41d4-ac3f-52015effcd99'	System	13 Sep 2020 23:22:15
User entered 'Yes (Y)'	System	13 Sep 2020 23:22:15

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f12f5856-f937-41d4-ac3f-52015effcd99'	System	13 Sep 2020 23:22:15
User entered '98.1'	System	13 Sep 2020 23:22:15

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:11', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f12f5856-f937-41d4-ac3f-52015effcd99'	System	13 Sep 2020 23:22:15
User entered 'No (N)'	System	13 Sep 2020 23:22:15

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:14', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f12f5856-f937-41d4-ac3f-52015effcd99'	System	13 Sep 2020 23:22:15
User entered '13 Sep 2020 18:22'	System	13 Sep 2020 23:22:15

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:17:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '11f0371e-277a-43ee-8967-0dbec1215599'	System	07 Sep 2020 20:18:13
User entered 'None (1)'	System	07 Sep 2020 20:18:13

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '11f0371e-277a-43ee-8967-0dbec1215599'	System	07 Sep 2020 20:18:13
User entered 'No (N)'	System	07 Sep 2020 20:18:13

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:05', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '11f0371e-277a-43ee-8967-0dbec1215599'	System	07 Sep 2020 20:18:13
User entered 'No (N)'	System	07 Sep 2020 20:18:13

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '11f0371e-277a-43ee-8967-0dbec1215599'	System	07 Sep 2020 20:18:13
User entered 'None (1)'	System	07 Sep 2020 20:18:13

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:11', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '11f0371e-277a-43ee-8967-0dbec1215599'	System	07 Sep 2020 20:18:13
User entered '07 Sep 2020 15:18'	System	07 Sep 2020 20:18:13

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 14:08'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 16:38'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:12:56', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c86cf177-0d10-453b-8386-8097b72f78b9'	System	07 Sep 2020 23:13:23
User entered 'None (1)'	System	07 Sep 2020 23:13:23

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c86cf177-0d10-453b-8386-8097b72f78b9'	System	07 Sep 2020 23:13:23
User entered 'No (N)'	System	07 Sep 2020 23:13:23

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:06', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c86cf177-0d10-453b-8386-8097b72f78b9'	System	07 Sep 2020 23:13:23
User entered 'No (N)'	System	07 Sep 2020 23:13:23

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:09', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c86cf177-0d10-453b-8386-8097b72f78b9'	System	07 Sep 2020 23:13:23
User entered 'None (1)'	System	07 Sep 2020 23:13:23

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:17', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c86cf177-0d10-453b-8386-8097b72f78b9'	System	07 Sep 2020 23:13:23
User entered '07 Sep 2020 18:13'	System	07 Sep 2020 23:13:23

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 17:33'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 2'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:42:35', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810ff78cfc3'	System	08 Sep 2020 22:43:33
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:01', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810fff78cfc3'	System	08 Sep 2020 22:43:33
User entered 'Yes (Y)'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:42:58', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810fff78cfc3'	System	08 Sep 2020 22:43:33
User entered '100'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:06', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810fff78cfc3'	System	08 Sep 2020 22:43:33
User entered 'Yes (Y)'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:16', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810fff78cfc3'	System	08 Sep 2020 22:43:33
User entered '1'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810ff78cfc3'	System	08 Sep 2020 22:43:33
User entered 'None (1)'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:31', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c30c4638-839a-4deb-94e7-810fff78cfc3'	System	08 Sep 2020 22:43:33
User entered '08 Sep 2020 17:43'	System	08 Sep 2020 22:43:33

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 3'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:15:23', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cdfa4483-cab5-46a9-ad28-2df0cfd9a46f'	System	09 Sep 2020 21:17:25
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 21:17:25

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:16:14', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cdfa4483-cab5-46a9-ad28-2df0cfd9a46f'	System	09 Sep 2020 21:17:25
User entered 'No (N)'	System	09 Sep 2020 21:17:25

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:16:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cdfa4483-cab5-46a9-ad28-2df0cfd9a46f' User entered 'Yes (Y)'	System	09 Sep 2020 21:17:25
	System	09 Sep 2020 21:17:25

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cdfa4483-cab5-46a9-ad28-2df0cfd9a46f' User entered '1'	System	09 Sep 2020 21:17:25
	System	09 Sep 2020 21:17:25

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:12', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cdfa4483-cab5-46a9-ad28-2df0cfd9a46f'	System	09 Sep 2020 21:17:25
User entered 'None (1)'	System	09 Sep 2020 21:17:25

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'cdfa4483-cab5-46a9-ad28-2df0cfd9a46f' User entered '09 Sep 2020 16:17'	System	09 Sep 2020 21:17:25
	System	09 Sep 2020 21:17:25

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 4'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '81fee59b-ee45-4b0c-be92-4607a4c04fce'	System	10 Sep 2020 21:54:10
User entered 'None (1)'	System	10 Sep 2020 21:54:10

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '81fee59b-ee45-4b0c-be92-4607a4c04fce' User entered 'No (N)'	System	10 Sep 2020 21:54:10
	System	10 Sep 2020 21:54:10

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:53:57', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '81fee59b-ee45-4b0c-be92-4607a4c04fce' User entered 'No (N)'	System	10 Sep 2020 21:54:10
	System	10 Sep 2020 21:54:10

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '81fee59b-ee45-4b0c-be92-4607a4c04fce' User entered 'None (1)'	System	10 Sep 2020 21:54:10
	System	10 Sep 2020 21:54:10

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:05', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '81fee59b-ee45-4b0c-be92-4607a4c04fce' User entered '10 Sep 2020 16:54'	System	10 Sep 2020 21:54:10
	System	10 Sep 2020 21:54:10

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 5'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:55:56', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f546371-ee8f-4dcb-8888-d9ca80124c96'	System	11 Sep 2020 21:56:30
User entered 'None (1)'	System	11 Sep 2020 21:56:30

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f546371-ee8f-4dcb-8888-d9ca80124c96'	System	11 Sep 2020 21:56:30
User entered 'No (N)'	System	11 Sep 2020 21:56:30

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:07', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f546371-ee8f-4dcb-8888-d9ca80124c96'	System	11 Sep 2020 21:56:30
User entered 'No (N)'	System	11 Sep 2020 21:56:30

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:10', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f546371-ee8f-4dcb-8888-d9ca80124c96'	System	11 Sep 2020 21:56:30
User entered 'None (1)'	System	11 Sep 2020 21:56:30

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:12', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f546371-ee8f-4dcb-8888-d9ca80124c96'	System	11 Sep 2020 21:56:30
User entered '11 Sep 2020 16:56'	System	11 Sep 2020 21:56:30

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 6'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:25', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f6e7bb98-2b8a-41f9-bf94-52f33a0e43c5'	System	13 Sep 2020 00:21:44
User entered 'None (1)'	System	13 Sep 2020 00:21:44

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:31', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f6e7bb98-2b8a-41f9-bf94-52f33a0e43c5'	System	13 Sep 2020 00:21:44
User entered 'No (N)'	System	13 Sep 2020 00:21:44

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:35', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f6e7bb98-2b8a-41f9-bf94-52f33a0e43c5'	System	13 Sep 2020 00:21:44
User entered 'No (N)'	System	13 Sep 2020 00:21:44

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:39', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f6e7bb98-2b8a-41f9-bf94-52f33a0e43c5'	System	13 Sep 2020 00:21:44
User entered 'None (1)'	System	13 Sep 2020 00:21:44

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:41', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f6e7bb98-2b8a-41f9-bf94-52f33a0e43c5'	System	13 Sep 2020 00:21:44
User entered '12 Sep 2020 19:21'	System	13 Sep 2020 00:21:44

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 7'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f50fdfb9-4252-4060-b8cf-69edb3c727e7'	System	13 Sep 2020 23:22:36
User entered 'None (1)'	System	13 Sep 2020 23:22:36

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f50fdb9-4252-4060-b8cf-69edb3c727e7'	System	13 Sep 2020 23:22:36
User entered 'No (N)'	System	13 Sep 2020 23:22:36

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:27', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f50fdb9-4252-4060-b8cf-69edb3c727e7'	System	13 Sep 2020 23:22:36
User entered 'No (N)'	System	13 Sep 2020 23:22:36

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:29', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f50fdfb9-4252-4060-b8cf-69edb3c727e7'	System	13 Sep 2020 23:22:36
User entered 'None (1)'	System	13 Sep 2020 23:22:36

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:32', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f50fdfb9-4252-4060-b8cf-69edb3c727e7' User entered '13 Sep 2020 18:22'	System	13 Sep 2020 23:22:36
	System	13 Sep 2020 23:22:36

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:16', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'None (0)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:19', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'None (0)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'None (0)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:24', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'None (0)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:26', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'None (0)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'None (0)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:31', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered 'No (N)'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T15:18:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9ebc45a1-e224-4159-8a51-6119be52c8b4' User entered '07 Sep 2020 15:18'	System	07 Sep 2020 20:18:38
	System	07 Sep 2020 20:18:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 14:08'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 16:38'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 1, after vaccination (at home)'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111'	System	07 Sep 2020 23:14:00
User entered 'None (0)'	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:39', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111' User entered 'None (0)'	System	07 Sep 2020 23:14:00
	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:41', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111'	System	07 Sep 2020 23:14:00
User entered 'None (0)'	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:44', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111' User entered 'None (0)'	System	07 Sep 2020 23:14:00
	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111' User entered 'None (0)'	System	07 Sep 2020 23:14:00
	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111'	System	07 Sep 2020 23:14:00
User entered 'None (0)'	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111'	System	07 Sep 2020 23:14:00
User entered 'No (N)'	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-07T18:13:54', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'dfa2a677-1ad3-41b7-a4ec-91e2e45df111' User entered '07 Sep 2020 18:13'	System	07 Sep 2020 23:14:00
	System	07 Sep 2020 23:14:00

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '07 Sep 2020 17:33'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '08 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 2'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'None (0)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:41', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'None (0)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:45', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'None (0)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'None (0)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'None (0)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:43:56', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'None (0)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:44:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82'	System	08 Sep 2020 22:44:07
User entered 'No (N)'	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-08T17:44:03', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e18d4e6d-d6cb-402f-b727-5e5e0e83fc82' User entered '08 Sep 2020 17:44'	System	08 Sep 2020 22:44:07
	System	08 Sep 2020 22:44:07

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 3'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:26', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226'	System	09 Sep 2020 21:17:49
User entered 'None (0)'	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226' User entered 'None (0)'	System	09 Sep 2020 21:17:49
	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:31', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226' User entered 'None (0)'	System	09 Sep 2020 21:17:49
	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226'	System	09 Sep 2020 21:17:49
User entered 'None (0)'	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226'	System	09 Sep 2020 21:17:49
User entered 'None (0)'	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226'	System	09 Sep 2020 21:17:49
User entered 'None (0)'	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:41', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226'	System	09 Sep 2020 21:17:49
User entered 'No (N)'	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-09T16:17:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'f45f23d5-07a0-4cc8-898e-2a5eb1ffb226'	System	09 Sep 2020 21:17:49
User entered '09 Sep 2020 16:17'	System	09 Sep 2020 21:17:49

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 4'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:09', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered 'None (0)'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:12', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered 'None (0)'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74'	System	10 Sep 2020 21:54:28
User entered 'None (0)'	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:15', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered 'None (0)'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:17', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered 'None (0)'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:20', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered 'None (0)'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:22', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered 'No (N)'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-10T16:54:24', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '0cbbd1bb-b07f-4966-bf24-0162dab73b74' User entered '10 Sep 2020 16:54'	System	10 Sep 2020 21:54:28
	System	10 Sep 2020 21:54:28

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '10 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 5'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:17', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered 'None (0)'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:19', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered 'None (0)'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:21', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d'	System	11 Sep 2020 21:56:38
User entered 'None (0)'	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:23', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered 'None (0)'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:25', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered 'None (0)'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:27', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered 'None (0)'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:30', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered 'No (N)'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-11T16:56:33', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'e2f67f6d-cb04-4f80-9677-056a2e501c7d' User entered '11 Sep 2020 16:56'	System	11 Sep 2020 21:56:38
	System	11 Sep 2020 21:56:38

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '11 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 6'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:45', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd' User entered 'None (0)'	System	13 Sep 2020 00:22:08
	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd' User entered 'None (0)'	System	13 Sep 2020 00:22:08
	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:50', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd' User entered 'None (0)'	System	13 Sep 2020 00:22:08
	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd' User entered 'None (0)'	System	13 Sep 2020 00:22:08
	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:54', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd' User entered 'None (0)'	System	13 Sep 2020 00:22:08
	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:21:57', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd'	System	13 Sep 2020 00:22:08
User entered 'None (0)'	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:22:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd' User entered 'No (N)'	System	13 Sep 2020 00:22:08
	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-12T19:22:02', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f3f5838-3b01-42dc-9c11-9d707aae67bd'	System	13 Sep 2020 00:22:08
User entered '12 Sep 2020 19:22'	System	13 Sep 2020 00:22:08

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '12 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	07 Sep 2020 18:51:37
User entered 'Day 7'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:36', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'None (0)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'None (0)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:40', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'None (0)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:43', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'None (0)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'None (0)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:48', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'None (0)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered 'No (N)'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-09-13T18:22:53', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '42f67813-4124-4e3b-b50c-ef6782ca84cd' User entered '13 Sep 2020 18:22'	System	13 Sep 2020 23:22:55
	System	13 Sep 2020 23:22:55

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '13 Sep 2020 12:00'	System	07 Sep 2020 18:51:37

US3312008

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:00:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
User entered '14 Sep 2020 11:59'	System	07 Sep 2020 18:51:37

US3312008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:18:23
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:27:19

US3312008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:18:23
User entered '14 Sep 2020'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:27:19

US3312008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:18:23
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:27:19

US3312008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:18:23
User entered empty.	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:27:19

US3312008

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:18:26
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Sep 2020 13:27:21

US3312008

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	15 Sep 2020 13:27:21

US3312008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:34:39
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:59:20

US3312008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:34:39
User entered '21 Sep 2020'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:59:20

US3312008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:34:39
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:59:20

US3312008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:34:39
User entered empty.	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:59:20

US3312008

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:34:42
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	22 Sep 2020 17:59:11

US3312008

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	22 Sep 2020 17:59:11

US3312008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:35:11
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	30 Sep 2020 23:31:15

US3312008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:35:11
User entered '28 Sep 2020'	Monica Atwood (b) (4) (b) (4)	30 Sep 2020 23:31:15

US3312008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:35:11
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	30 Sep 2020 23:31:15

US3312008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:35:11
User entered empty.	Monica Atwood (b) (4) (b) (4)	30 Sep 2020 23:31:15

US3312008

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:35:13
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	30 Sep 2020 23:31:04

US3312008

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	30 Sep 2020 23:31:04

US3312008

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:20:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:53:38

US3312008

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:20:27
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:53:38

US3312008

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:20:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 16:53:38

US3312008

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'VISIT3'	System	09 Oct 2020 16:53:38

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '13:15'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '5 Oct 2020 13:15'	System	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '97' F	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '56'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'bpm'	System	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '14'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'breaths/min'	System	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '142'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:22:44
User entered '82'	(b) (4), (b) (6)	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'mmHg'	System	09 Oct 2020 16:54:10

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46

US3312008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46

US3312008

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:23:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:58:11

US3312008

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:23:00
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:58:11

US3312008

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:23:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:59:27

US3312008

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:23:11
User entered '5 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 16:59:27

US3312008

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:23:11
User entered '13:51'	(b) (4), (b) (6)	09 Oct 2020 16:59:27

US3312008

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '5 Oct 2020 13:51'	System	09 Oct 2020 16:59:27

US3312008

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	15 Feb 2021 21:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:23:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 16:59:33

US3312008

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered '1'	System	09 Oct 2020 16:59:33

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 64'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-10-12T14:17:59', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'fe766c63-2f23-4024-b507-5d00dc4f3ea5'	System	12 Oct 2020 19:18:14
User entered 'No (N)'	System	12 Oct 2020 19:18:14

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-10-12T14:18:04', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'fe766c63-2f23-4024-b507-5d00dc4f3ea5'	System	12 Oct 2020 19:18:14
User entered 'No (N)'	System	12 Oct 2020 19:18:14

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-10-12T14:18:12', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'fe766c63-2f23-4024-b507-5d00dc4f3ea5' User entered '12 Oct 2020 14:18:12'	System	12 Oct 2020 19:18:14
	System	12 Oct 2020 19:18:14

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 71'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 78'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-10-27T12:58:32', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5c74ded7-54ed-4d64-bc94-971819f2478a'	System	27 Oct 2020 17:58:46
User entered 'No (N)'	System	27 Oct 2020 17:58:46

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-10-27T12:58:37', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5c74ded7-54ed-4d64-bc94-971819f2478a'	System	27 Oct 2020 17:58:46
User entered 'No (N)'	System	27 Oct 2020 17:58:46

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-10-27T12:58:42', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '5c74ded7-54ed-4d64-bc94-971819f2478a' User entered '27 Oct 2020 12:58:42'	System	27 Oct 2020 17:58:46
	System	27 Oct 2020 17:58:46

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:08:59
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 92'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:00:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:00:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:00:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

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**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3312008

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)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

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US3312008

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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered 'Day 99'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 18:57:49

US3312008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:19:52
Data entry locked.	System	10 Aug 2020 18:57:49
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 18:57:49

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-16T14:19:06', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd412f5e1-e7ea-458a-8eb8-8b52aab8e30a'	System	16 Dec 2020 20:19:15
User entered 'No (N)'	System	16 Dec 2020 20:19:15

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-16T14:19:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd412f5e1-e7ea-458a-8eb8-8b52aab8e30a'	System	16 Dec 2020 20:19:15
User entered 'No (N)'	System	16 Dec 2020 20:19:15

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-16T14:19:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'd412f5e1-e7ea-458a-8eb8-8b52aab8e30a'	System	16 Dec 2020 20:19:15
User entered '16 Dec 2020 14:19:13'	System	16 Dec 2020 20:19:15

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-23T15:20:44', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'fda06f50-0574-4a63-97f0-c65e78d26fa8'	System	23 Dec 2020 21:21:20
User entered 'No (N)'	System	23 Dec 2020 21:21:20

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-23T15:20:49', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'fda06f50-0574-4a63-97f0-c65e78d26fa8'	System	23 Dec 2020 21:21:20
User entered 'No (N)'	System	23 Dec 2020 21:21:20

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-23T15:21:08', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'fda06f50-0574-4a63-97f0-c65e78d26fa8' User entered '23 Dec 2020 15:21:08'	System	23 Dec 2020 21:21:20
	System	23 Dec 2020 21:21:20

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-30T15:48:42', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'be0c788b-14b6-4bb7-8d9c-c8df30ce713b'	System	30 Dec 2020 21:48:56
User entered 'No (N)'	System	30 Dec 2020 21:48:56

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-30T15:48:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'be0c788b-14b6-4bb7-8d9c-c8df30ce713b'	System	30 Dec 2020 21:48:56
User entered 'No (N)'	System	30 Dec 2020 21:48:56

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2020-12-30T15:48:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'be0c788b-14b6-4bb7-8d9c-c8df30ce713b' User entered '30 Dec 2020 15:48:52'	System	30 Dec 2020 21:48:56
	System	30 Dec 2020 21:48:56

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-07T04:05:16', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '65809217-6f4b-4698-b366-ff87d998e0b1'	System	07 Jan 2021 22:28:36
User entered 'No (N)'	System	07 Jan 2021 22:28:36

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-07T04:05:18', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '65809217-6f4b-4698-b366-ff87d998e0b1' User entered 'No (N)'	System	07 Jan 2021 22:28:36
	System	07 Jan 2021 22:28:36

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-07T04:05:23', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '65809217-6f4b-4698-b366-ff87d998e0b1' User entered '07 Jan 2021 04:05:23'	System	07 Jan 2021 22:28:36
	System	07 Jan 2021 22:28:36

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-13T16:53:28', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '543b492e-88d4-4a04-b34e-9c23b0cb9391'	System	20 Jan 2021 22:13:56
User entered 'No (N)'	System	20 Jan 2021 22:13:56

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-13T16:53:30', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '543b492e-88d4-4a04-b34e-9c23b0cb9391'	System	20 Jan 2021 22:13:56
User entered 'No (N)'	System	20 Jan 2021 22:13:56

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-13T16:53:34', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '543b492e-88d4-4a04-b34e-9c23b0cb9391' User entered '13 Jan 2021 16:53:34'	System	20 Jan 2021 22:13:56
	System	20 Jan 2021 22:13:56

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-20T16:13:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ef40ef97-38eb-4b88-8134-f369692ec7be'	System	20 Jan 2021 22:14:13
User entered 'No (N)'	System	20 Jan 2021 22:14:13

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-20T16:13:57', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ef40ef97-38eb-4b88-8134-f369692ec7be'	System	20 Jan 2021 22:14:13
User entered 'No (N)'	System	20 Jan 2021 22:14:13

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-20T16:14:04', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ef40ef97-38eb-4b88-8134-f369692ec7be' User entered '20 Jan 2021 16:14:04'	System	20 Jan 2021 22:14:13
	System	20 Jan 2021 22:14:13

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-27T10:14:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '04aacad5-d2ab-4456-af26-ffb9f7ec6375'	System	05 Feb 2021 14:38:43
User entered 'No (N)'	System	05 Feb 2021 14:38:43

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-27T10:14:51', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '04aacad5-d2ab-4456-af26-ffb9f7ec6375'	System	05 Feb 2021 14:38:43
User entered 'No (N)'	System	05 Feb 2021 14:38:43

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-01-27T10:14:59', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '04aacad5-d2ab-4456-af26-ffb9f7ec6375'	System	05 Feb 2021 14:38:43
User entered '27 Jan 2021 10:14:59'	System	05 Feb 2021 14:38:43

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-05T08:33:13', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9d5bec89-2be4-46ae-8a8b-1e425a237889'	System	05 Feb 2021 14:38:44
User entered 'No (N)'	System	05 Feb 2021 14:38:44

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-05T08:33:16', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9d5bec89-2be4-46ae-8a8b-1e425a237889'	System	05 Feb 2021 14:38:44
User entered 'No (N)'	System	05 Feb 2021 14:38:44

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-05T08:33:22', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '9d5bec89-2be4-46ae-8a8b-1e425a237889' User entered '05 Feb 2021 08:33:22'	System	05 Feb 2021 14:38:44
	System	05 Feb 2021 14:38:44

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-10T10:53:38', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '2abf8fdf-0ec4-444a-9996-8798c8126530'	System	17 Feb 2021 16:36:06
User entered 'No (N)'	System	17 Feb 2021 16:36:06

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-10T10:53:41', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '2abf8fdf-0ec4-444a-9996-8798c8126530'	System	17 Feb 2021 16:36:06
User entered 'No (N)'	System	17 Feb 2021 16:36:06

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-10T10:53:50', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '2abf8fdf-0ec4-444a-9996-8798c8126530'	System	17 Feb 2021 16:36:06
User entered '10 Feb 2021 10:53:50'	System	17 Feb 2021 16:36:06

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-17T10:34:43', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ea81cdcb-4684-4a15-88cc-4da177a0f642'	System	17 Feb 2021 16:36:06
User entered 'No (N)'	System	17 Feb 2021 16:36:06

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-17T10:34:46', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ea81cdcb-4684-4a15-88cc-4da177a0f642'	System	17 Feb 2021 16:36:06
User entered 'No (N)'	System	17 Feb 2021 16:36:06

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-17T10:34:52', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'ea81cdcb-4684-4a15-88cc-4da177a0f642' User entered '17 Feb 2021 10:34:52'	System	17 Feb 2021 16:36:06
	System	17 Feb 2021 16:36:06

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-24T16:50:26-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f6e6c33-4297-4442-8ffd-f8377177c917'	System	03 Mar 2021 22:08:25
User entered 'No (N)'	System	03 Mar 2021 22:08:25

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-24T16:50:29-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f6e6c33-4297-4442-8ffd-f8377177c917'	System	03 Mar 2021 22:08:25
User entered 'No (N)'	System	03 Mar 2021 22:08:25

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-02-24T16:50:33-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '3f6e6c33-4297-4442-8ffd-f8377177c917'	System	03 Mar 2021 22:08:25
User entered '24 Feb 2021 22:50:33'	System	03 Mar 2021 22:08:25

**US3312008**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-03T16:07:29-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '05039c74-9fe7-40d4-b0d5-3ed8bb6b09bb'	System	03 Mar 2021 22:08:36
User entered 'No (N)'	System	03 Mar 2021 22:08:36

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-03T16:07:31-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '05039c74-9fe7-40d4-b0d5-3ed8bb6b09bb'	System	03 Mar 2021 22:08:36
User entered 'No (N)'	System	03 Mar 2021 22:08:36

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-03T16:07:35-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '05039c74-9fe7-40d4-b0d5-3ed8bb6b09bb' User entered '03 Mar 2021 16:07:35'	System	03 Mar 2021 22:08:36
	System	03 Mar 2021 22:08:36

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-11T15:15:23-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '988ccfd7-3bea-4bcd-89f8-969deb6fec6f'	System	11 Mar 2021 21:16:38
User entered 'No (N)'	System	11 Mar 2021 21:16:38

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-11T15:15:26-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '988ccfd7-3bea-4bcd-89f8-969deb6fec6f'	System	11 Mar 2021 21:16:38
User entered 'No (N)'	System	11 Mar 2021 21:16:38

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-11T15:15:31-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '988ccfd7-3bea-4bcd-89f8-969deb6fec6f' User entered '11 Mar 2021 15:15:31'	System	11 Mar 2021 21:16:38
	System	11 Mar 2021 21:16:38

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-17T20:39:48-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '293c2719-a6ce-4bca-aba0-cee6b9cf17e8'	System	25 Mar 2021 18:00:33
User entered 'No (N)'	System	25 Mar 2021 18:00:33

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-17T20:39:51-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '293c2719-a6ce-4bca-aba0-cee6b9cf17e8'	System	25 Mar 2021 18:00:33
User entered 'No (N)'	System	25 Mar 2021 18:00:33

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-17T20:40:02-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '293c2719-a6ce-4bca-aba0-cee6b9cf17e8'	System	25 Mar 2021 18:00:33
User entered '17 Mar 2021 20:40:02'	System	25 Mar 2021 18:00:33

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-24T12:13:29-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7f5a03d7-c3dd-418a-9876-c4102115d243'	System	25 Mar 2021 18:00:39
User entered 'No (N)'	System	25 Mar 2021 18:00:39

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-24T12:13:32-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7f5a03d7-c3dd-418a-9876-c4102115d243'	System	25 Mar 2021 18:00:39
User entered 'No (N)'	System	25 Mar 2021 18:00:39

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-24T12:13:36-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '7f5a03d7-c3dd-418a-9876-c4102115d243'	System	25 Mar 2021 18:00:39
User entered '24 Mar 2021 12:13:36'	System	25 Mar 2021 18:00:39

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-31T11:47:20-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '16ae4e73-9e40-46a3-9fa0-ce22330f5917'	System	31 Mar 2021 16:47:43
User entered 'No (N)'	System	31 Mar 2021 16:47:43

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-31T11:47:23-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '16ae4e73-9e40-46a3-9fa0-ce22330f5917'	System	31 Mar 2021 16:47:43
User entered 'No (N)'	System	31 Mar 2021 16:47:43

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-31T11:47:28-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '16ae4e73-9e40-46a3-9fa0-ce22330f5917'	System	31 Mar 2021 16:47:43
User entered '31 Mar 2021 11:47:28'	System	31 Mar 2021 16:47:43

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-04-07T16:41:07-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '277a27f1-56f7-4fac-87d5-2e695558723f'	System	07 Apr 2021 21:43:10
User entered 'No (N)'	System	07 Apr 2021 21:43:10

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-04-07T16:41:09-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '277a27f1-56f7-4fac-87d5-2e695558723f' User entered 'No (N)'	System	07 Apr 2021 21:43:10
	System	07 Apr 2021 21:43:10

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-04-07T16:41:14-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '277a27f1-56f7-4fac-87d5-2e695558723f'	System	07 Apr 2021 21:43:10
User entered '07 Apr 2021 16:41:14'	System	07 Apr 2021 21:43:10

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-04-22T17:23:23-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c1492e7b-03f5-4cf8-880d-496971bcc956'	System	23 Apr 2021 18:35:02
User entered 'No (N)'	System	23 Apr 2021 18:35:02

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

Have you been exposed to someone with 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 (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-04-22T17:23:26-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c1492e7b-03f5-4cf8-880d-496971bcc956'	System	23 Apr 2021 18:35:02
User entered 'No (N)'	System	23 Apr 2021 18:35:02

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-04-22T17:23:31-05:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: 'c1492e7b-03f5-4cf8-880d-496971bcc956'	System	23 Apr 2021 18:35:02
User entered '22 Apr 2021 17:23:31'	System	23 Apr 2021 18:35:02

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:19:52

US3312008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:00:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:19:52

**US3312008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:00:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:19:52
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:19:52

US3312008

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-11T15:15:47-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '48373090-a5ba-440c-a45f-984a4ac6c1c5'	System	11 Mar 2021 21:16:41
User entered 'No (N)'	System	11 Mar 2021 21:16:41

US3312008

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:00:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:39:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7D8EB906-6782-46AA-BE37-D7676B87EDA8)', Time: '2021-03-11T15:15:52-06:00', User OID: 'PatientReportedOutcome (US3312008)', ODM File OID: '48373090-a5ba-440c-a45f-984a4ac6c1c5' User entered '11 Mar 2021 15:15:52'	System	11 Mar 2021 21:16:41
	System	11 Mar 2021 21:16:41

US3312008

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:25:49
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:39:24

US3312008

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:25:49
User entered '02 Nov 2020'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:39:24

US3312008

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:25:49
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:39:24

US3312008

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:25:49
User entered empty.	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:39:24

US3312008

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:25:57
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	03 Nov 2020 17:39:28

US3312008

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:39:46
User entered 'I'	System	03 Nov 2020 17:39:28

US3312008

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:47:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4) (b) (4)	07 Dec 2020 16:01:01

US3312008

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:47:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '7 Dec 2020'	(b) (4) Kelly Moen (b) (4)	07 Dec 2020 16:01:01

US3312008

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:47:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelly Moen (b) (4)	07 Dec 2020 16:01:01

US3312008

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:47:44
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered empty.	(b) (4) Kelly Moen (b) (4) (b) (4)	07 Dec 2020 16:01:01

US3312008

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:06
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) Kelly Moen (b) (4)	07 Dec 2020 16:01:07

US3312008

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User entered 'I'	System	07 Dec 2020 16:01:07

US3312008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:56:16
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 16:54:31

US3312008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:56:16
User entered '04 Jan 2021'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 16:54:31

US3312008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:56:16
User entered 'Contact Made (CONTACT MADE)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 16:54:31

US3312008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:56:16
User entered empty.	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 16:54:31

US3312008

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 16:56:38
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 16:54:38

US3312008

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User entered '1'	System	05 Jan 2021 16:54:38

US3312008

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 15:15:09

US3312008

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:21
User entered '01 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 15:15:09

US3312008

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 15:15:09

US3312008

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:21
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 15:15:09

US3312008

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 15:13:59

US3312008

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:28:05
User entered 'I'	System	02 Feb 2021 15:13:59

US3312008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:51:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:35

US3312008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:51:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:35

US3312008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:51:54
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:35

US3312008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered 'VISIT4'	System	10 Mar 2021 17:26:35

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:01
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered empty.	System	29 Mar 2021 17:35:25

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56

US3312008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:00:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56

US3312008

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:41

US3312008

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:00:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:08
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:41

US3312008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:57

US3312008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:57

US3312008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:18
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered '13:22'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:57

US3312008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '05 Mar 2021 13:22'	System	10 Mar 2021 17:26:57

US3312008

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:52:23
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:03

US3312008

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:30:56
User entered '1'	System	10 Mar 2021 17:27:03

US3312008

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:24:36

US3312008

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:24:36

US3312008

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:24:36

US3312008

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:00:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:24:36

US3312008

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:24:39

US3312008

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:00:53

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 17:24:39

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US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:51

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:51

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[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 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:38
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:51

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:00:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 22:14:51

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:06:02

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:06:02

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:51:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:51:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:48:47
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User entered empty.	System	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:00:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User entered empty.	System	11 Jan 2021 22:14:16

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:28

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:28

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:49:05
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '12:39'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:28

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:00:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User entered '11 Jan 2021 12:39'	System	11 Jan 2021 22:14:28

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:38

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:38

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:50:20
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered '12:38'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 22:14:38

US3312008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:00:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:10
User entered '11 Jan 2021 12:38'	System	11 Jan 2021 22:14:38

US3312008

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:00:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:24:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:37:42
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:01:50

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Dog bite - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:04:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:04:30
Data point term sent to Coder	System	05 Jan 2021 17:03:38
User entered 'DOG BITE LEFT SHIN'	Monica Atwood (b) (4)	05 Jan 2021 17:03:08
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '20 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
User entered empty.	System	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '30 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
User entered empty.	System	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	12 Mar 2021 15:41:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:03:08
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:03:08
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

None

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:22
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '1'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
User entered '0'	System	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50
User entered '1'	System	05 Jan 2021 17:03:08

US3312008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:50

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Facial bones fracture - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:34:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 17:34:29
Data point term sent to Coder	System	05 Jan 2021 17:05:42
User entered 'FACIAL FRACTURES X3'	Monica Atwood (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '31 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
User entered empty.	System	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:58
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:58
User entered empty.	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
User entered empty.	System	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:04:45
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:04:45
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:04:45
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '1'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:38:23
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 15:41:17
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
User entered '0'	System	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52
User entered '1'	System	05 Jan 2021 17:04:45

US3312008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:52

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:20:05
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered	(b) (4)	22 Apr 2021 12:20:17
'USA-US300-2021-mRNA-1273-P301000024'	System	22 Apr 2021 12:20:17
User entered 'New'	(b) (4), (b) (6)	22 Apr 2021 12:20:17

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery insufficiency, LLT: Coronary artery insufficiency - version MedDRA\23.0.	Coder Import (b) (4)	30 Apr 2021 17:59:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Apr 2021 17:59:59
Data point term sent to Coder	System	30 Apr 2021 17:17:42
DataPoint Un-verified.	Carlos Fierro (b) (4)	30 Apr 2021 17:17:10
	(b) (4)	
Coding entries removed.	Carlos Fierro (b) (4)	30 Apr 2021 17:17:10
	(b) (4)	
Signature has been broken.	Carlos Fierro (b) (4)	30 Apr 2021 17:17:10
	(b) (4)	
User entered 'Coronary artery insufficiency (involving the left anterior descending and left circumflex coronary arteries)' reason for change: New Information	Carlos Fierro (b) (4)	30 Apr 2021 17:17:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
	(b) (4)	
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 15:21:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Apr 2021 15:21:26
Data point term sent to Coder	System	21 Apr 2021 15:09:18
User entered 'myocardial infarction'	(b) (4), (b) (6)	21 Apr 2021 15:08:47
	(b) (4)	

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [Redacted]	30 Apr 2021 19:18:14
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	Carlos Fierro (b) (4) [Redacted]	30 Apr 2021 19:09:02
Signature has been broken.	Carlos Fierro (b) (4) [Redacted]	30 Apr 2021 17:17:41
User entered '15 Feb 2021' reason for change: New Information	Carlos Fierro (b) (4) [Redacted]	30 Apr 2021 17:17:10
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6) [Redacted]	30 Apr 2021 12:29:18
User signature succeeded.	Carlos Fierro (b) (4) [Redacted]	23 Apr 2021 16:55:22
User entered '15 Apr 2021'	(b) (4), (b) (6) [Redacted]	22 Apr 2021 20:38:18
		21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:18:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject did not receive heart catheterization for further evaluation of coronary insufficiency and for definitive therapy such as coronary stent or balloon angioplasty due to history of chronic kidney disease and missing kidney. Coronary condition is therefore ongoing and managed medically instead.' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	30 Apr 2021 17:20:05
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:28:41
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:08:47

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US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '18 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:20:01
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'see above query response, ongoing' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	30 Apr 2021 17:22:02
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:29:25
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify if medications used to treat coronary artery disease were also to treat event, myocardial infarction. Please consider adding coronary artery disease to medical history if subject has history of same.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:19:48
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:19:41
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:19:38
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:19:32
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Medical Records sent to PVG' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:41:49
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'See medical records sent to PVG' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:41:39
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Neg Covid test15Ap2021, unknown type' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 17:41:16

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 17:39:23
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 17:39:23
User entered 'Subj reports HOSPITALIZATION FROM 15 APR 2021 TO 18 APR 2021. ON ROUGHLY 25 MAR 2021, SUBJECT BEGAN EXPERIENCING DULL, ACHING, INTERMITTENT PAIN IN LEFT ARM, WHICH SHE PRESUMED TO BE RELATED TO HX OF LYMPHEDEMA SECONDARY TO MASTECTOMY. PAIN PERSISTED FOR SEVERAL WEEKS PROMPTING SCHEDULED PCP VISIT 15 APR 2021 REPORTEDLY, PCP IDENTIFIED BP OF 198/90, ABNORMAL EKG, FOLLOWED BY IMMEDIATE REFERRAL TO LOCAL ED, SUBJECT WAS ADMITTED FOR NONINVASIVE CARDIAC WORKUP INVOLVING ECHO AND CHEMICAL STRESS TEST, REVEALING SUBACUTE MI. SHE WAS D/C'D ON 18 APR 2021 WITH NEW RX FOR CARVEDILOL, HYDRALAZINE, ROSUVASTATIN, NORVASC, AND ASA. SUBJECT AWAITING OUTPATIENT CARDIAC REHAB AND F/U WITH CARDIOLOGIST ON 12 MAY 2021. PENDING RECEIPT OF MED recs. Update 30Apr21: updated SAE start date to Feb2021, Subject was admitted for unstable angina and benign essential HTN. Workup revealed elevated BNP, rales, and peripheral edema. Subject was diagnosed with acute diastolic CHF with preserved EF, MI ruled out. MPI showed reversible ischemia in LAD and left circumflex, prompting recommendation for LHC. Subject elected medical management given hx of CKD3 and right nephrectomy. She was d/c'd on 18 Apr 2021 with new rx for carvedilol, hydralazine, rosuvastatin, norvasc, and ASA. Subject awaiting outpatient cardiac rehab and f/u with cardiologist on 12 May 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 17:39:23

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify if medications used to treat coronary artery disease were also to treat event, myocardial infarction. Please consider adding coronary artery disease to medical history if subject has history of same.' answered with 'No myocardial infarction. Med history, con meds updated. See updated narrative.' (Site from Safety).	Carlos Fierro (b) (4) (b) (4)	30 Apr 2021 17:23:14
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:35:25
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:29:32
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:28:59
User opened query 'PV Query: Please clarify if medications used to treat coronary artery disease were also to treat event, myocardial infarction. Please consider adding coronary artery disease to medical history if subject has history of same.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 12:28:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:55:22
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject contacted site on 21 Apr 2021 to report hospitalization from 15 Apr 2021 to 18 Apr 2021. On roughly 25 Mar 2021, subject began experiencing dull, aching, intermittent pain in left arm, which she presumed to be related to hx of lymphedema secondary to mastectomy. Pain persisted for several weeks, prompting scheduled PCP visit on 15 Apr 2021. Reportedly, PCP identified BP of 198/90 and abnormal EKG, followed by immediate referral to local ED, St. Luke's South. Subject was admitted for noninvasive cardiac workup involving echocardiogram and chemical stress test, revealing subacute MI. She was d/c'd on 18 Apr 2021 with new rx for carvedilol, hydralazine, rosuvastatin, norvasc, and ASA. Subject awaiting outpatient cardiac rehab and f/u with cardiologist on 12 May 2021. Pending receipt of medical records'	(b) (4), (b) (6)	21 Apr 2021 15:08:47

US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 15:08:47

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US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 15:08:47

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US3312008

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 15:08:47

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US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLG: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4)	30 Apr 2021 18:53:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Apr 2021 18:53:04
	(b) (4)	
Data point term sent to Coder	System	30 Apr 2021 18:51:58
User entered 'congestive heart failure'	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

**US3312008**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:00:53**

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:51:50

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US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:52:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 18:52:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:52:20
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:51:50
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:52:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 18:52:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:52:20
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:51:50
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:52:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 18:52:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:52:20
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:51:50
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

None

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Apr 2021 18:52:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Apr 2021 18:51:50
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:52:20
User entered '0'	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:52:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 18:52:20
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:52:20
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 18:51:50
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:51:50

**US3312008**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:00:53**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 18:51:50

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US3312008

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:00:53

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 18:51:50

---

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:00:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:24:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:36:09
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:44:55

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:50:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:50:20
Data point term sent to Coder User entered 'diltiazem'	System Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:23 11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'hypertension'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '120'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:09:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 19:49:03
User entered 'un UNK 2010'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:49:03

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:49:03

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US3312008

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:00:53**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:49:03

---

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 19:49:03

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:51:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:51:21
Data point term sent to Coder	System	11 Aug 2020 19:50:24
User entered 'metroprolol'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'hypertension'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '100'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:09:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 19:50:15
User entered 'un UNK 2010'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:50:15

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:50:15

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:50:15

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 19:50:15

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:52:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 19:52:22
Data point term sent to Coder	System	11 Aug 2020 19:51:28
User entered 'hydrochlorothiazide'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'hypertension'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '25'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:09:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 19:51:13
User entered 'un UNK 2010'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Un-verified.	(b) (4) Karol Moore (b) (4)	03 Nov 2020 17:37:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	03 Nov 2020 17:37:07
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Un-verified.	(b) (4) Karol Moore (b) (4)	03 Nov 2020 17:37:07
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4) Karol Moore (b) (4)	03 Nov 2020 17:37:07
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User entered '1'	System	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User entered '1'	System	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:46
User entered '804 (804)'	System	11 Aug 2020 19:51:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:02:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:02:21
Data point term sent to Coder	System	11 Aug 2020 20:00:40
User entered 'fluoxetine'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'anxiety'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '20'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:10:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 20:00:05
User entered 'un UNK 1980'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:00:05

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:00:05

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:00:05

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 20:00:05

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:49:12
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 06:49:12
Data point term sent to Coder	System	11 Aug 2020 20:02:45
User entered 'magnesium'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'bilateral foot cramps'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '500'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 14:23:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 20:01:50
User entered 'un UNK 2019'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:01:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:01:50

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:01:50

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 20:01:50

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:06:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:06:14
Data point term sent to Coder	System	11 Aug 2020 20:05:50
User entered 'Vitamin D'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'health maintenance'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '1'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'tablet (TABLET)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:10:31
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 20:05:20
User entered 'un UNK 2014'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:05:20

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:05:20

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:05:20

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 20:05:20

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:55:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:55:13
Data point term sent to Coder	System	11 Aug 2020 20:09:55
User entered 'Vitamin B complex'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'general health maintenance'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '1'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'tablet (TABLET)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'once daily (QD)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:10:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 20:09:11
User entered 'un UNK 2014'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:09:11

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:09:11

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 20:09:11

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 20:09:11

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 10:23:22
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 Aug 2020 10:23:22
Data point term sent to Coder	System	11 Aug 2020 20:11:59
User entered 'Aspirin'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User closed query 'Per MM: Please revise the indication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 08:04:30
Query 'Per MM: Please revise the indication.' answered with 'CORRECT AS ENTERED. HELPS SUBJECT SLEEP' (Site from DM).	Karol Moore (b) (4) (b) (4)	21 Oct 2020 15:51:25
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:37:48
User opened query 'Per MM: Please revise the indication.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:16:41
User entered 'difficulty sleeping'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '325'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'mg (mg)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'as needed (PRN)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Oral (ORAL)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 13:10:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 20:11:13
User entered 'un UNK 2015'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered '0'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:20
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	11 Aug 2020 20:11:20
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	11 Aug 2020 20:11:13
User entered empty.	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:37:48
User entered 'No (N)'	Kelly Moen (b) (4) (b) (4)	11 Aug 2020 20:11:13

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:11:13

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**US3312008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:00:53**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:11:13

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:11:13

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:34:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 17:34:30
Data point term sent to Coder	System	05 Jan 2021 17:06:42
User entered 'HYDROCODONE/ACETAMINOPHEN'	Monica Atwood (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'FACIAL FRACTURES X3'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '5/325'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'mg (mg)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'as needed (PRN)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Oral (ORAL)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '31 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:02:14
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	26 Mar 2021 15:44:42
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Mar 2021 15:44:28
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:41:50
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '07 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Karol Moore (b) (4)	26 Mar 2021 15:44:28
	(b) (4)	
	Monica Atwood (b) (4)	05 Jan 2021 17:06:36
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
User entered empty.	System	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
User entered empty.	System	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:53
User entered empty.	System	05 Jan 2021 17:06:36

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Jan 2021 17:10:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Jan 2021 17:10:29
Data point term sent to Coder	System	05 Jan 2021 17:07:43
User entered 'CLINDAMYCIN'	Monica Atwood (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'FACIAL FRACTURES X3'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '300'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'mg (mg)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'three times daily (TID)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Oral (ORAL)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '31 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:02:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	26 Mar 2021 15:45:45
User entered 'No (N)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Mar 2021 15:45:29
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 02:41:58
User entered 'Yes (Y)'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 21:26:40
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Mar 2021 15:45:29
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Mar 2021 15:45:13
User entered '07 Jan 2021' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	26 Mar 2021 15:45:13
User entered empty.	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
User entered '3'	System	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
User entered '1'	System	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:01
User entered '804 (804)'	System	05 Jan 2021 17:07:29

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: INULIN;LACTOBACILLUS RHAMNOSUS, PRODUCTSYNONYM: CULTURELLE HEALTH & WELLNESS PROBIOTIC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:40:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:40:38
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 21:26:40
Data point term sent to Coder	System	05 Apr 2021 21:25:57
Coding entries removed.	Monica Atwood (b) (4) (b) (4)	05 Apr 2021 21:25:07
User entered 'CULTURELLE PROBIOTICS (LACTOBACILLUS/INULIN)' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	05 Apr 2021 21:25:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS NOS, PRODUCTSYNONYM: CULTURELLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:27:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:27:30
Data point term sent to Coder	System	05 Jan 2021 17:12:45
User entered 'CULTURELLE PROBIOTICS'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'GASTROINTESTINAL HEALTH MAINTENANCE'	(b) (4) Monica Atwood (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (consider: 40mg/200mg).' ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:22:13
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	05 Apr 2021 21:26:40
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (consider: 40mg/200mg).' ' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	05 Apr 2021 21:25:29
User entered '40/200' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	05 Apr 2021 21:25:07
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (consider: 40mg/200mg).' ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:08:08
User entered '200'	Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'mg (mg)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'twice daily (BID)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Oral (ORAL)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '31 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	26 Mar 2021 15:46:21
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Jan 2021 17:11:51
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
	(b) (4)	
User entered '07 Jan 2021' reason for change: Data Entry Error	Karol Moore (b) (4)	26 Mar 2021 15:46:21
	(b) (4)	
User entered empty.	Monica Atwood (b) (4)	05 Jan 2021 17:11:51
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
User entered '2'	System	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
User entered '1'	System	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:04
User entered '804 (804)'	System	05 Jan 2021 17:11:51

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Jan 2021 17:28:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Jan 2021 17:28:29
Data point term sent to Coder	System	05 Jan 2021 17:14:47
User entered 'TDAP (TETANUS DIPHTHERIA PERTUSSIS) BOOSTER VACCINE'	Monica Atwood (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Yes (Y)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'TETANUS PROPHYLAXIS'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '0.5'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'mL (mL)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'once (ONCE)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '21 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '21 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
User entered empty.	System	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
User entered empty.	System	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:08
User entered empty.	System	05 Jan 2021 17:14:18

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Jan 2021 17:29:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Jan 2021 17:29:29
Data point term sent to Coder	System	05 Jan 2021 17:15:48
User entered 'CLINDAMYCIN'	Monica Atwood (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'DOG BITE LEFT SHIN'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '300'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'mg (mg)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:18:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Jan 2021 17:18:34
User entered 'three times daily (TID)' reason for change: Data Entry Error	Monica Atwood (b) (4)	05 Jan 2021 17:18:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Jan 2021 17:15:17
User entered empty.	System	05 Jan 2021 17:15:17
	Monica Atwood (b) (4)	05 Jan 2021 17:15:17
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'Oral (ORAL)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered empty.	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '21 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered '30 Dec 2020'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:22
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 21:26:40
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4) (b) (4)	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
User entered '3'	System	05 Jan 2021 17:18:34
User entered empty.	System	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
User entered '1'	System	05 Jan 2021 17:18:34
User entered empty.	System	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:33:13
User entered '804 (804)'	System	05 Jan 2021 17:18:34
User entered empty.	System	05 Jan 2021 17:15:17

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:34:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:34:14
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	30 Apr 2021 18:33:25 30 Apr 2021 18:32:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:20:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 16:20:07
Data point term sent to Coder User entered 'carvedilol'	System Karol Moore (b) (4) (b) (4)	21 Apr 2021 16:19:18 21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
DataPoint Un-verified.	(b) (4)	30 Apr 2021 18:32:52
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 18:32:52
User entered 'Congestive heart failure' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:32:52
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'coronary artery disease'	(b) (4)	21 Apr 2021 16:18:31
	Karol Moore (b) (4)	
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '6.25'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '18 Apr 2021'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 16:18:38
User entered 'No (N)'	Karol Moore (b) (4)	21 Apr 2021 16:18:31
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		21 Apr 2021 16:18:38
User opened query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		21 Apr 2021 16:18:31
User entered empty.	Karol Moore (b) (4) (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:18:31

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 16:18:31

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 16:18:31

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 16:18:31

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:53:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:53:38
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	30 Apr 2021 18:34:26 30 Apr 2021 18:33:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:37:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:37:45
Data point term sent to Coder User entered 'hydralazine'	System Karol Moore (b) (4) (b) (4)	21 Apr 2021 16:19:20 21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
DataPoint Un-verified.	(b) (4)	30 Apr 2021 18:33:40
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 18:33:40
User entered 'Congestive heart failure' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:33:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'coronary artery disease'	(b) (4)	21 Apr 2021 16:19:14
	Karol Moore (b) (4)	
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '25'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'twice daily (BID)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '18 Apr 2021'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 16:19:14

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 16:19:14

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 16:19:14

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 16:21:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 16:21:02
Data point term sent to Coder	System	21 Apr 2021 16:20:23
User entered 'rosuvastatin'	Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'coronary artery disease'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '40'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '18 Apr 2021'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 16:19:59

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 16:19:59

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 16:19:59

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 16:19:59

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:35:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 18:35:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	30 Apr 2021 18:34:26 30 Apr 2021 18:34:15
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	22 Apr 2021 20:38:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 17:27:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 17:27:29
Data point term sent to Coder User entered 'norvasc'	System Karol Moore (b) (4) (b) (4)	21 Apr 2021 17:14:33 21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 19:09:02
DataPoint Un-verified.	(b) (4)	30 Apr 2021 18:34:15
Signature has been broken.	(b) (4), (b) (6)	30 Apr 2021 18:34:15
User entered 'Congestive heart failure' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 18:34:15
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'coronary artery disease'	(b) (4)	21 Apr 2021 17:13:50
	Karol Moore (b) (4)	
	(b) (4)	

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '10'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '18 Apr 2021'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:13:50

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:13:50

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:13:50

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 17:27:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 17:27:29
Data point term sent to Coder User entered 'aspirin'	System Karol Moore (b) (4)	21 Apr 2021 17:14:33 21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'coronary artery disease'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '81'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'mg (mg)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'once daily (QD)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Oral (ORAL)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '18 Apr 2021'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '0'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered empty.	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:58:31
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	21 Apr 2021 17:14:14

US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:14:14

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US3312008

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:00:53**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 17:14:14

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US3312008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:00:53

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 17:14:14

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US3312008

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:00:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:40:32
User signature succeeded.	Carlos Fierro (b) (4)	05 Apr 2021 17:19:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 15:13:35

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'USA-US300-2021-MRNA-1273-P301000024'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Yes (Y)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Yes (Y)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Carlos'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Fierro'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '16300 College Blvd'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Shawnee'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'KS'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '66219'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'US'	System	22 Apr 2021 12:21:06

**US3312008**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000024**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:20:38
User entered '1'	System	22 Apr 2021 12:21:06

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'USA-US300-2021-MRNA-1273-P301000024'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Yes (Y)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Yes (Y)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Carlos'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Fierro'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '16300 College Blvd'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Shawnee'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'KS'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '66219'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'US'	System	22 Apr 2021 12:21:06

**US3312008**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000024**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:20:38
User entered '1'	System	22 Apr 2021 12:21:06

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
User entered '22/Apr/2021 08:21'	(b) (4) System	22 Apr 2021 12:21:06

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:00:53

**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)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 12:21:06

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'USA-US300-2021-MRNA-1273-P301000024'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Yes (Y)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Yes (Y)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'No (N)'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Carlos'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Fierro'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '16300 College Blvd'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'Shawnee'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'KS'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered '66219'	System	22 Apr 2021 12:20:17

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 17:00:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:54:45
User signature succeeded.	Carlos Fierro (b) (4)	22 Apr 2021 20:38:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:22:08
User entered 'US'	System	22 Apr 2021 12:21:06

**US3312008**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000024**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:00:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 19:20:38
User entered '1'	System	22 Apr 2021 12:21:06

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:53

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 20:48:53
User entered '30/Apr/2021 15:20'	(b) (4) System	30 Apr 2021 19:20:38

US3312008

Folder: SAE USA-US300-2021-MRNA-1273-P301000024

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:00:53

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	30 Apr 2021 20:48:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:20:38