

US3792094 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:52:10

All time stamps listed in this document are displayed in GMT

US3792094

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 21:59:48

Generated On: 10 Jun 2021 09:52:10

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[Participant ID](#)

US3792094

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

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US3792094

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3792094

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Date of Informed Consent ( <i>dd MMM yyyy</i> )	9 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3792094

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 21:59:50

Generated On: 10 Jun 2021 09:52:10

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	DIABETIC NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	DIABETES MELLITUS, TYPE 2
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	HPERTENSION
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)	_____

US3792094

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	CARPAL TUNNEL SYNDROME, BILATERAL
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3792094

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	TINNITUS
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	CLOSED FRACTURE OF PHALANX OF LEFT 3RD TOE
Start date (dd MMM yyyy)	01 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Condition	DIABETIC RETINOPATHY OF BOTH EYES
Start date (dd MMM yyyy)	18 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	12:29 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:29
Height ( <i>xxx.x</i> )	68.5 in
Weight ( <i>xxx.x</i> )	330.0 lb
BMI ( <i>xxx.x</i> )	49.54989 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:50

Generated On: 10 Jun 2021 09:52:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:50

Generated On: 10 Jun 2021 09:52:10

### 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

WARES VENDOR AT (b) (6)

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

What was the date of randomization? (dd MMM yyyy) 09 OCT 2020

What was the participant's randomization number? 191513

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 ☒

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 19 Feb 2021 21:59:51**

**Generated On: 10 Jun 2021 09:52:10**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:29
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:37
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	167 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

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) 9 OCT 2020

What was the treatment time? (00:00-23:59) 13:08 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 13:08

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	12:33 (24 HR)
Collection date and time (derived)	9 OCT 2020 12:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:38	9 OCT 2020 12:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**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):

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

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

PC Time Stamp 09 OCT 2020 13:48

PC Open Date & Time 09 OCT 2020 13:28

PC Close Date & Time 09 OCT 2020 15:58

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

PC Time Stamp	09 OCT 2020 16:56
PC Open Date & Time	09 OCT 2020 16:53
PC Close Date & Time	10 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**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	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 16:02

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 12:29

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 13:05

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 12:35

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 17:01

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 13:50

PC Open Date & Time

09 OCT 2020 13:28

PC Close Date & Time

09 OCT 2020 15:58

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**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

09 OCT 2020 16:56

PC Open Date & Time

09 OCT 2020 16:53

PC Close Date & Time

10 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 12:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 16:03

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**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

12 OCT 2020 12:29

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 13:05

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 12:36

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 17:01

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**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 ☐

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 13:51
PC Open Date & Time	09 OCT 2020 13:28
PC Close Date & Time	09 OCT 2020 15:58

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**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 ☐

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 16:57
PC Open Date & Time	09 OCT 2020 16:53
PC Close Date & Time	10 OCT 2020 11:59



US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 16:03
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 12:30
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 13:06
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59



US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 12:37
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**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 ☒

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 17:02
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3792094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 11:39
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 13:09
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

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) 6 NOV 2020

What was the treatment time? (00:00-23:59) 12:19 (24 HR)

Treatment Date and Time (derived) 6 NOV 2020 12:19

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

What was the frequency of the study treatment dosing? ONCE

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

US3792094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 NOV 2020
Collection time (00:00-23:59)	11:43 (24 HR)
Collection date and time (derived)	6 NOV 2020 11:43



US3792094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Collection date (dd MMM yyyy)			6 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	6 NOV 2020 11:50
Nasopharyngeal Swab 2	No		

US3792094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 NOV 2020 13:13

PC Open Date & Time

06 NOV 2020 12:39

PC Close Date & Time

06 NOV 2020 15:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**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 95.4 °F

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

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

PC Time Stamp	06 NOV 2020 18:10
PC Open Date & Time	06 NOV 2020 16:04
PC Close Date & Time	07 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 NOV 2020 21:09

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 NOV 2020 19:55

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 NOV 2020 23:50

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 NOV 2020 23:57

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59



US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

11 NOV 2020 21:00

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 NOV 2020 19:39

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 NOV 2020 13:13

PC Open Date & Time

06 NOV 2020 12:39

PC Close Date & Time

06 NOV 2020 15:09

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**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

06 NOV 2020 18:11

PC Open Date & Time

06 NOV 2020 16:04

PC Close Date & Time

07 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 NOV 2020 21:10

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 NOV 2020 19:56

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**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

09 NOV 2020 23:50

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 NOV 2020 23:58

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 NOV 2020 21:00

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 NOV 2020 19:39

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**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 ☐

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

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

No ☒

Yes ☐

PC Time stamp	06 NOV 2020 13:14
PC Open Date & Time	06 NOV 2020 12:39
PC Close Date & Time	06 NOV 2020 15:09

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**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 ☐

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

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

No ☒

Yes ☐

PC Time stamp	06 NOV 2020 18:12
PC Open Date & Time	06 NOV 2020 16:04
PC Close Date & Time	07 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	07 NOV 2020 21:11
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59



US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	08 NOV 2020 19:56
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**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 ☒

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	09 NOV 2020 23:50
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	10 NOV 2020 23:58
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	11 NOV 2020 21:01
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59



US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Yes <input type="checkbox"/>	
PC Time stamp	12 NOV 2020 19:40
PC Open Date & Time	12 NOV 2020 12:00
PC Close Date & Time	13 NOV 2020 11:59

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3792094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3792094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:52

Generated On: 10 Jun 2021 09:52:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	11:13 (24 HR)
Vital Signs Date and Time (derived)	4 DEC 2020 11:13
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

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.*

US3792094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 DEC 2020
Collection time (00:00-23:59)	11:17 (24 HR)
Collection date and time (derived)	4 DEC 2020 11:17

US3792094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:51

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 61
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	08 DEC 2020 22:06:12
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 68
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	15 DEC 2020 13:48:19
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 04:49:57
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59



US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 11:32:19

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

<b>TIMEPOINT</b>	DAY 89
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 JAN 2021 06:44:09
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 05:49:11
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

Date and time of submission

17 JAN 2021 15:14:05

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 JAN 2021 20:39:03
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 FEB 2021 14:22:03
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 03:14:00
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 20:31:35

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59



US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 05:19:27

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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

01 MAR 2021 19:53:40

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 09:50:48

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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	16 MAR 2021 17:34:07
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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

22 MAR 2021 02:00:57

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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

29 MAR 2021 23:33:51

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 12:47:25

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 14:14:31

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59



US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 02:04:27
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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

26 APR 2021 12:03:43

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 04:28:05

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2022 23:59
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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

**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 ☐



**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2022 23:59

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US3792094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:10

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

**US3792094**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

11 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

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US3792094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:52:10

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 19:53:03

US3792094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3792094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:04:42

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 08 Apr 2021 22:51:03

**Generated On: 10 Jun 2021 09:52:10**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:51:03

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3792094**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3792094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3792094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:10

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.*

**US3792094**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>



**US3792094**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3792094**

**Folder: Covid-19 Assessment (2)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:52:10**

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"/>

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 21:59:48

Generated On: 10 Jun 2021 09:52:10

Date of Contact	2 FEB 2021
Time of Contact	14:00
Date and Time of Contact (derived)	2 FEB 2021 14:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

Date	29 JAN 2021
------	-------------

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

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

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

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

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

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

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

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 JAN 2021	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

Date	1 FEB 2021
------	------------

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

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

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

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

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

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

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

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

Date	5 FEB 2021
------	------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.0 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Symptom Day

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 28 Apr 2021 05:45:06

Generated On: 10 Jun 2021 09:52:10

Date of Visit	2 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	25 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	URGENT CARE
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:48

Generated On: 10 Jun 2021 09:52:10

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed: (b) (4) 19 Apr 2021 16:14:06**

**Generated On: 10 Jun 2021 09:52:10**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	4 FEB 2021
Day 5	Yes	6 FEB 2021
Day 7	Yes	8 FEB 2021
Day 9	Yes	10 FEB 2021
Day 14	Yes	15 FEB 2021
Day 21	Yes	22 FEB 2021
Day 28	Yes	5 MAR 2021

US3792094

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3792094

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	12:42 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 12:42
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3792094

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3792094

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 FEB 2021

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 10:03
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	94.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	171 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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.*

US3792094

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

5 MAR 2021

US3792094

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3792094

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

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3792094**

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

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 19 Feb 2021 21:59:49**

**Generated On: 10 Jun 2021 09:52:10**

Height	
Weight	
BMI (xxx.x)	

US3792094

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 12:20
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Height	
Weight	
BMI (xxx.x)	
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)	14 JAN 2021
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 13:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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.*



US3792094

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 12:45

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

US3792094

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	12:23 (24 HR)
Collection date and time (derived)	14 JAN 2021 12:23

US3792094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	12:28
Collection Date and Time (derived)	14 JAN 2021 12:28

US3792094

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3792094

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3792094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 14:45
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3792094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

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)	25 FEB 2021
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 15:47
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3792094

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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.*

US3792094

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

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

Treatment Date and Time (derived) 25 FEB 2021 15:15

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

US3792094

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:04:42

Generated On: 10 Jun 2021 09:52:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3792094

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:04:42

Generated On: 10 Jun 2021 09:52:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3792094

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3792094

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	12:32 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 12:32
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3792094

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

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.*

US3792094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:04:41

Generated On: 10 Jun 2021 09:52:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	31 MAR 2021 12:45

US3792094

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Nov 2020 23:31:49

Generated On: 10 Jun 2021 09:52:10

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID	USA-US057-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE KIDNEY INJURY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	22 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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SUB I NOTE: SPOKE WITH  
PATIENT FOR DAY 15 SAFETY  
FOLLOW UP PHONE CALL.  
WOKE UP TUESDAY MORNING  
10.20.20 AND HIS ENTIRE BODY  
WAS SWOLLEN. WENT TO THE  
HOSPITAL AND WAS  
ADMITTED. RELEASED  
YESTERDAY , (10/22/2020). HIS  
KIDNEY FUNCTION WAS DOWN  
TO 44%. WAS GIVEN LASIX,  
WHICH HELPED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID

Adverse event

WORSENING OF DIABETES  
MELLITUS

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 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 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 ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID	
Adverse event	RIGHT KIDNEY CYST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID	
Adverse event	DECREASED KIDNEY FUNCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 01 Apr 2021 21:04:31

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID

Adverse event

RIGHT GREAT TOENAIL INJURY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 01 Apr 2021 21:04:31

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID

Adverse event

UPPER RESPIRATORY  
INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 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 ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

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



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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 01 Apr 2021 21:04:31

Generated On: 10 Jun 2021 09:52:10

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 01 Apr 2021 21:04:31

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

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 21:59:48

Generated On: 10 Jun 2021 09:52:10

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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.

---

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication PREGABALIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC NEUROPATHY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication JARDIANCE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS, TYPE 2

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication CARVEDILOL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Apr 2021 16:14:05

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication BENIGN PROSTATIC  
HYPERPLASIA

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC NEUROPATHY

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication LOSARTIN

Prophylaxis Yes ☒  
No ☐

Indication RENAL PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication VASCEPA

Prophylaxis Yes ☐  
No ☒

Indication HYPERHOLESTEROLEMIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication BREO ELLIPTA  
(FLUTCASONE FUROATE  
VILANTEROL

Prophylaxis Yes ☐  
No ☒

Indication COPD

Dose per administration 200/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication INSULIN GLARGINE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 45

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication ACETAMINOPHEN 325MG /  
OXYCODONE 5

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	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)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication HUMALOG

Prophylaxis Yes ☐  
No ☒

Indication ELEVATED BLOOD GLUCOSE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication TRAZODONE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐  
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 04

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUEL	
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication INSULIN GLARGINE

Prophylaxis Yes ☐  
No ☒

Indication ELEVATED BLOOD GLUCOSE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication NOVALOG

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

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

6 TIMES PER DAY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication RIGHT GREAT TOENAIL INJURY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

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

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication UPPER RESPIRATORY  
INFECTION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication UPPER RESPIRATORY  
INFECTION

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	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)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication PROMETHAZINE DM  
(PROMETHAZINE  
6.25/DEXTROMETHORPHAN15M  
G)

Prophylaxis Yes ☐  
No ☒

Indication UPPER RESPIRATORY  
INFECTION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL CARPAL TUNNEL  
SYNDROME, LEFT SHOULDER  
OSTEOARTHRITIS

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	1 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL CARPAL TUNNEL  
SYNDROME, LEFT SHOULDER  
OSTEOARTHRITIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 19 Apr 2021 16:14:05

Generated On: 10 Jun 2021 09:52:10

	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)		4 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 21:59:48

Generated On: 10 Jun 2021 09:52:10

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 21:59:48

Generated On: 10 Jun 2021 09:52:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 OCT 2020	RENAL ULTRASOUND	Adverse Event	
22 OCT 2020	ECHOCARDIOGRAM	Adverse Event	
22 OCT 2020	CHEST X-RAY	Adverse Event	

US3792094

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:52:10

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



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:52:10

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 ☐

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

SAEID	USA-US057-2020-MRNA-1273-P301000001
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	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

SAEID	USA-US057-2020-MRNA-1273-P301000001
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	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/OCT/2020 22:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

SAEID	USA-US057-2020-MRNA-1273-P301000001
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	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/NOV/2020 19:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

SAEID	USA-US057-2020-MRNA-1273-P301000001
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	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/NOV/2020 06:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 21:59:49

Generated On: 10 Jun 2021 09:52:10

SAEID	USA-US057-2020-MRNA-1273-P301000001
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	ABRAM
Investigator's Last Name	BURGER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/JAN/2021 10:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3792094 (Prod: Hope Research Institute LLC - Hunt - PPDS)

**US3792094**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:52:10**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'US3792094'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 18:52:47



**US3792094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:43:03

**US3792094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 18:52:48

**US3792094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	09 Oct 2020 19:43:03

**US3792094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'SCRN'	System	09 Oct 2020 19:43:03

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 18:52:49

US3792094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 19:50:20
User entered '66' reason for change: Data Entry Error	System	09 Oct 2020 19:50:20
User opened query 'Data is required. Please complete.' (Site from System).	Norma Frederick (b) (4)	09 Oct 2020 19:50:20
User entered empty.	(b) (4)	
	System	09 Oct 2020 19:49:51
	Norma Frederick (b) (4)	09 Oct 2020 19:49:51
	(b) (4)	

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'YEARS'	System	09 Oct 2020 19:50:20
User entered empty.	System	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '66'	System	09 Oct 2020 19:43:55



**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Male (M)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'I'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51



**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:52:10**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:49:51

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered '9 Oct 2020'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Oct 2020'	System	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2020'	System	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered 'Amendment 4 (4)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:55



**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered empty.	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:43:55

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 18:52:48

**US3792094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:52:10**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'I'	System	09 Oct 2020 19:44:03

**US3792094**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:52:10**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 20:58:29
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:44:03

**US3792094**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:52:10**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:44:10

US3792094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 19:23:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 19:23:26
Data point term sent to Coder	System	06 Nov 2020 19:22:16
User entered 'DIABETIC NEUROPATHY'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16



**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'UN UNK 2011'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2011'	System	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2011'	System	06 Nov 2020 19:21:16

**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 19:21:16



**US3792094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 19:21:16

US3792094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:36:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:36:25
Data point term sent to Coder	System	06 Nov 2020 20:35:10
User entered 'diabetes mellitus, type 2'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2001'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2001'	System	06 Nov 2020 20:34:42



**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2001'	System	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:34:42

**US3792094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:34:42

US3792094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:36:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:36:26
Data point term sent to Coder	System	06 Nov 2020 20:35:09
User entered 'hypertension'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:35:06



**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2015'	System	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2015'	System	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:35:06

**US3792094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:35:06

US3792094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:37:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:37:21
Data point term sent to Coder	System	06 Nov 2020 20:36:10
User entered 'benign prostatic hyperplasia'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08



**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2015'	System	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2015'	System	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:36:08

**US3792094**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:36:08

US3792094

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:27
Data point term sent to Coder	System	06 Nov 2020 20:37:12
User entered 'acid reflux'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46



**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2008'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2008'	System	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2008'	System	06 Nov 2020 20:36:46

**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:36:46



**US3792094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:36:46

US3792094

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
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.	Coder Import (b) (4)	06 Nov 2020 20:38:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:28
Data point term sent to Coder	System	06 Nov 2020 20:38:13
User entered 'hypercholesterolemia'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2015'	System	06 Nov 2020 20:37:34



**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2015'	System	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:37:34

**US3792094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:37:34

US3792094

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:38:29
Data point term sent to Coder	System	06 Nov 2020 20:38:13
User entered 'insomnia'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2010'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:37:54



**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2010'	System	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2010'	System	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:37:54

**US3792094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:37:54

US3792094

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 21:24:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 21:24:32
Data point term sent to Coder	System	06 Nov 2020 20:40:15
User entered 'carpal tunnel syndrome, bilateral'	Norma Frederick (b) (4)	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2014'	Norma Frederick (b) (4)	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:40:03



**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2014'	System	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2014'	System	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:40:03

**US3792094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:40:03

US3792094

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 18:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 18:59:47
Data point term sent to Coder	System	13 Nov 2020 18:59:09
Coding entries removed.	Scarlett Hammett (b) (4)	13 Nov 2020 18:59:08
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 18:59:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 20:42:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 20:42:24
Data point term sent to Coder	System	06 Nov 2020 20:41:18
User entered 'COPD'	Norma Frederick (b) (4)	06 Nov 2020 20:40:25



**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 1975'	Norma Frederick (b) (4)	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 1975'	System	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '1975'	System	06 Nov 2020 20:40:25

**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:40:25



**US3792094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:40:25

US3792094

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:02:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:02:48
Data point term sent to Coder	System	13 Nov 2020 19:02:13
User entered 'LEFT SHOULDER OSTEOARTHRITIS'	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'UN UNK 2005'	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2005'	System	13 Nov 2020 19:01:45



**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2005'	System	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	13 Nov 2020 19:01:45

**US3792094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	13 Nov 2020 19:01:45

US3792094

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:22
Data point term sent to Coder	System	06 Nov 2020 20:44:23
User entered 'gout'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2010'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:43:27



**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2010'	System	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2010'	System	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:43:27

**US3792094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:43:27

US3792094

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:23
Data point term sent to Coder	System	06 Nov 2020 20:44:23
User entered 'obesity'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 1972'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44



**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 1972'	System	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '1972'	System	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:43:44

**US3792094**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:43:44

US3792094

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:45:22
Data point term sent to Coder	System	06 Nov 2020 20:44:23
User entered 'tinnitus'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23



**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'un UNK 2009'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jan 2009'	System	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2009'	System	06 Nov 2020 20:44:23

**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:44:23



**US3792094**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:44:23

US3792094

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Foot fracture - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 08:58:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 08:58:33
Data point term sent to Coder	System	06 Nov 2020 20:45:27
User entered 'closed fracture of phalanx of left 3rd toe'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '01 Sep 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Sep 2020'	System	06 Nov 2020 20:45:06



**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2020'	System	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:45:06

**US3792094**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:45:06

US3792094

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Diabetic retinopathy, LLT: Diabetic retinopathy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 23:45:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 23:45:26
Data point term sent to Coder	System	06 Nov 2020 20:46:28
User entered 'diabetic retinopathy of both eyes'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '18 Jun 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:45:40



**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'Jun 2020'	System	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '2020'	System	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered empty.	System	06 Nov 2020 20:45:40

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '12:29'	Norma Frederick (b) (4)	09 Oct 2020 19:46:08



**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '9 Oct 2020 12:29'	System	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '68.5' in	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:46:08
DataPoint set to visible.	(b) (4)	
	System	09 Oct 2020 19:44:03

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '330.0' lb	Norma Frederick (b) (4)	09 Oct 2020 19:46:08
DataPoint set to visible.	System	09 Oct 2020 19:44:03

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered '49.54989'	System	09 Oct 2020 19:46:08
DataPoint set to visible.	System	09 Oct 2020 19:44:03

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'kg/m2'	System	09 Oct 2020 19:46:08
DataPoint set to visible.	System	09 Oct 2020 19:44:03

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08



**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'bpm'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'breaths/min'	System	09 Oct 2020 19:46:08

US3792094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'mmHg'	System	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:46:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User entered 'mmHg'	System	09 Oct 2020 19:46:08



US3792094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08

**US3792094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08

**US3792094**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:46:16

**US3792094**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:46:16

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05



US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

**US3792094**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:52:10**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05



US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'wares vendor at (b) (6) '	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

**US3792094**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:52:10**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'I'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05



US3792094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:59:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'mobile home'	Norma Frederick (b) (4)	09 Oct 2020 19:47:05

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:23

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:47:23

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:23

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'VISIT1'	System	09 Oct 2020 19:47:23

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 19:47:41

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:10

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '191513'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 19:47:41

US3792094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 19:47:41



**US3792094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:52:10**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:52:10**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:52:10**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:52:10**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:52:10**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:52:10**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:47:48
DataPoint set to visible.	System	09 Oct 2020 19:43:55

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52



**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '12:29'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '9 Oct 2020 12:29'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '97.6' F	Norma Frederick (b) (4)	09 Oct 2020 19:51:52



US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '57'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'bpm'	System	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '15'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'breaths/min'	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:10

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '154'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	09 Oct 2020 19:51:52



**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '85'	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 23:52:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Oct 2020 19:51:52
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '9 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '13:37' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	



**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '9 Oct 2020 13:37'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '64' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'bpm'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'breaths/min'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52



US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User closed query 'Per CDM: Systolic BP is out of range <80 or >155 is considered as grade 3 per protocol. Please indicate if CS or NCS and report as AE, if appropriate or else clarif' (Site from DM).	(b) (4)	19 Nov 2020 20:39:29
Query 'Per CDM: Systolic BP is out of range <80 or >155 is considered as grade 3 per protocol. Please indicate if CS or NCS and report as AE, if appropriate or else clarif' answered with 'Per Sub-I bp is NCS' (Site from DM).	Ann Marie Milliken (b) (4)	18 Nov 2020 19:07:39
User opened query 'Per CDM: Systolic BP is out of range <80 or >155 is considered as grade 3 per protocol. Please indicate if CS or NCS and report as AE, if appropriate or else clarif' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 20:47:55
User entered '167' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '92' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:52:59
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	09 Oct 2020 19:51:52
	(b) (4)	

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	04 Nov 2020 23:52:59
User entered empty.	System	09 Oct 2020 19:51:52

US3792094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:48:34

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:48:34

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 20:16:54



US3792094

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '13:08'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '9 Oct 2020 13:08'	System	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	09 Oct 2020 20:16:54

US3792094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'ONCE'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 20:16:54



US3792094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:25

US3792094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:10

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 09-OCT-2020. However, collection date is missing in GCL. Please confirm if 09-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 09:56:53
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 09-OCT-2020. However, collection date is missing in GCL. Please confirm if 09-OCT-2020 is correct date to update in GCL records.' answered with 'confirmed visit date is 10/9/2020' (Site from DM).	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 01:35:33
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 09-OCT-2020. However, collection date is missing in GCL. Please confirm if 09-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:52:47
User entered '9 Oct 2020'	Norma Frederick (b) (4) (b) (4)	09 Oct 2020 19:49:25

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '12:33'	Norma Frederick (b) (4)	09 Oct 2020 19:49:25

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '9 Oct 2020 12:33'	System	09 Oct 2020 19:49:25

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:52:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '9 Oct 2020'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '12:38'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00



**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '9 Oct 2020 12:38'	System	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered empty.	System	09 Oct 2020 19:49:00

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	09 Oct 2020 19:48:41

**US3792094**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	09 Oct 2020 19:48:41

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 20:16:54



US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:45:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered 'Yes (Y)'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:47:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered '98.1'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:47:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered 'Yes (Y)'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'This was recorded in error' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:07:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:48:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	Ann Marie Milliken (b) (4)	18 Nov 2020 19:09:48
User entered '1'	System	09 Oct 2020 20:48:56

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'This was recorded in error.' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:07:53
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'This was recorded in error.' (Site from System).	Ann Marie Milliken (b) (4)	18 Nov 2020 19:09:59
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	09 Oct 2020 20:48:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:48:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered '1'	System	09 Oct 2020 20:48:56

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:48:50', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5ca55cf6-5cef-4004-bb73-83a3340116a8'	System	09 Oct 2020 20:48:56
User entered '09 Oct 2020 13:48'	System	09 Oct 2020 20:48:56

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 13:28'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 15:58'	System	09 Oct 2020 20:16:54



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:55:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered 'Yes (Y)'	System	09 Oct 2020 23:56:23

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered '96.8'	System	09 Oct 2020 23:56:23

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered 'No (N)'	System	09 Oct 2020 23:56:23

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a50280d7-e648-406f-9e43-1e734d188fc0'	System	09 Oct 2020 23:56:23
User entered '09 Oct 2020 16:56'	System	09 Oct 2020 23:56:23

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 16:53'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 2'	System	09 Oct 2020 20:16:54



US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:01:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered 'Yes (Y)'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:08', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered '97.5'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered 'Yes (Y)'	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'This was recorded in error' (Site from System).	(b) (4), (b) (6)	22 Nov 2020 10:08:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ann Marie Milliken	18 Nov 2020 19:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	(b) (4)	
User entered '1'	System	10 Oct 2020 19:02:54
	System	10 Oct 2020 19:02:54
	System	10 Oct 2020 19:02:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered '0'	System	10 Oct 2020 19:02:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:02:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '719d3b92-bcd9-4f03-9cf7-64e47e871717'	System	10 Oct 2020 19:02:54
User entered '10 Oct 2020 12:02'	System	10 Oct 2020 19:02:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 20:16:54



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 3'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered 'Yes (Y)'	System	11 Oct 2020 23:02:51

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered '97.5'	System	11 Oct 2020 23:02:51

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:42', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered 'No (N)'	System	11 Oct 2020 23:02:51

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ad5df36b-b03c-456f-8b2d-ee839fdf64b8'	System	11 Oct 2020 23:02:51
User entered '11 Oct 2020 16:02'	System	11 Oct 2020 23:02:51

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 4'	System	09 Oct 2020 20:16:54



US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:28:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered 'Yes (Y)'	System	12 Oct 2020 19:29:25

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:28:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered '97.5'	System	12 Oct 2020 19:29:25

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered 'No (N)'	System	12 Oct 2020 19:29:25

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c959652c-066f-482d-be87-1440626840d1'	System	12 Oct 2020 19:29:25
User entered '12 Oct 2020 12:29'	System	12 Oct 2020 19:29:25

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 5'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered 'Yes (Y)'	System	13 Oct 2020 20:05:31



US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered '95.5'	System	13 Oct 2020 20:05:31

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered 'No (N)'	System	13 Oct 2020 20:05:31

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '789e37eb-5c78-4b27-ac20-ae17b0a12f31'	System	13 Oct 2020 20:05:31
User entered '13 Oct 2020 13:05'	System	13 Oct 2020 20:05:31

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 6'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered 'Yes (Y)'	System	14 Oct 2020 19:35:52

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered '97.0'	System	14 Oct 2020 19:35:52



US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:42', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered 'No (N)'	System	14 Oct 2020 19:35:52

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8726df91-77da-4d32-9f77-f714c20869d2'	System	14 Oct 2020 19:35:52
User entered '14 Oct 2020 12:35'	System	14 Oct 2020 19:35:52

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 7'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:08', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f'	System	16 Oct 2020 00:01:32
User entered 'Yes (Y)'	System	16 Oct 2020 00:01:32

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:17', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f'	System	16 Oct 2020 00:01:32
User entered '97.8'	System	16 Oct 2020 00:01:32

US3792094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f'	System	16 Oct 2020 00:01:32
User entered 'No (N)'	System	16 Oct 2020 00:01:32



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '44cb4832-a902-475c-b80d-8065264a127f'	System	16 Oct 2020 00:01:32
User entered '15 Oct 2020 17:01'	System	16 Oct 2020 00:01:32

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:49:17', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'None (1)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:33', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'No (N)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'No (N)'	System	09 Oct 2020 20:51:07

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered 'None (1)'	System	09 Oct 2020 20:51:07



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:50:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5d9eefe4-6e94-454c-9edd-1d16754f593d'	System	09 Oct 2020 20:51:07
User entered '09 Oct 2020 13:50'	System	09 Oct 2020 20:51:07

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 13:28'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 15:58'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'None (1)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'No (N)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'No (N)'	System	09 Oct 2020 23:56:56

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeee06c458b'	System	09 Oct 2020 23:56:56
User entered 'None (1)'	System	09 Oct 2020 23:56:56



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:56:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8b44256d-50e9-4c4e-a1d2-eeee06c458b'	System	09 Oct 2020 23:56:56
User entered '09 Oct 2020 16:56'	System	09 Oct 2020 23:56:56

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 16:53'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 2'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:33', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'None (1)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'No (N)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'No (N)'	System	10 Oct 2020 19:04:01

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:50', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered 'None (1)'	System	10 Oct 2020 19:04:01



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:03:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c0dd7105-89fb-4e82-8675-837009ad6814'	System	10 Oct 2020 19:04:01
User entered '10 Oct 2020 12:03'	System	10 Oct 2020 19:04:01

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 3'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'None (1)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:02:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'No (N)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'No (N)'	System	11 Oct 2020 23:03:18

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered 'None (1)'	System	11 Oct 2020 23:03:18



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f6df2fdd-04b8-4741-8ed3-4d5ee8f0e26b'	System	11 Oct 2020 23:03:18
User entered '11 Oct 2020 16:03'	System	11 Oct 2020 23:03:18

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 4'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'None (1)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'No (N)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'No (N)'	System	12 Oct 2020 19:29:53

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered 'None (1)'	System	12 Oct 2020 19:29:53



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:50', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '34848fb7-2e8f-4d70-a950-9ad36d7b617c'	System	12 Oct 2020 19:29:53
User entered '12 Oct 2020 12:29'	System	12 Oct 2020 19:29:53

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 5'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'None (1)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'No (N)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'No (N)'	System	13 Oct 2020 20:06:00

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered 'None (1)'	System	13 Oct 2020 20:06:00



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:05:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3a4feebc-380c-49d3-91fe-308c1a5fcaaf'	System	13 Oct 2020 20:06:00
User entered '13 Oct 2020 13:05'	System	13 Oct 2020 20:06:00

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 6'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:35:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'None (1)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'No (N)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'No (N)'	System	14 Oct 2020 19:36:31

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered 'None (1)'	System	14 Oct 2020 19:36:31



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3d93cdc2-9c0e-4ee8-8e27-ee80129a8151'	System	14 Oct 2020 19:36:31
User entered '14 Oct 2020 12:36'	System	14 Oct 2020 19:36:31

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 7'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'None (1)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'No (N)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'No (N)'	System	16 Oct 2020 00:02:03

US3792094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered 'None (1)'	System	16 Oct 2020 00:02:03



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:01:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'dba20477-7006-47de-ba17-fafe2f688a93'	System	16 Oct 2020 00:02:03
User entered '15 Oct 2020 17:01'	System	16 Oct 2020 00:02:03

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:08', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'None (0)'	System	09 Oct 2020 20:51:43

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered 'No (N)'	System	09 Oct 2020 20:51:43

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T13:51:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '78be4bbe-c284-4ae3-b4ac-566a3810ba0a'	System	09 Oct 2020 20:51:43
User entered '09 Oct 2020 13:51'	System	09 Oct 2020 20:51:43

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 13:28'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 15:58'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02



US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'None (0)'	System	09 Oct 2020 23:58:02

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered 'No (N)'	System	09 Oct 2020 23:58:02

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-09T16:57:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cd63350c-f7d3-4edf-9884-8df93765acc4'	System	09 Oct 2020 23:58:02
User entered '09 Oct 2020 16:57'	System	09 Oct 2020 23:58:02

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Oct 2020 16:53'	System	09 Oct 2020 20:16:54



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 2'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:01', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'None (0)'	System	10 Oct 2020 19:04:37



US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered 'No (N)'	System	10 Oct 2020 19:04:37

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-10T12:04:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24033187-85df-480c-a009-f743aa5a7222'	System	10 Oct 2020 19:04:37
User entered '10 Oct 2020 12:04'	System	10 Oct 2020 19:04:37

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 3'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49



US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:33', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'None (0)'	System	11 Oct 2020 23:03:49

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered 'No (N)'	System	11 Oct 2020 23:03:49

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-11T16:03:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '901bbf07-7dc8-4251-b48b-60e1537bb085'	System	11 Oct 2020 23:03:49
User entered '11 Oct 2020 16:03'	System	11 Oct 2020 23:03:49

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 4'	System	09 Oct 2020 20:16:54



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:29:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:20', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'None (0)'	System	12 Oct 2020 19:30:39

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered 'No (N)'	System	12 Oct 2020 19:30:39

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-12T12:30:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6d45bc4a-85b3-4e0b-9a75-28a3780e5965'	System	12 Oct 2020 19:30:39
User entered '12 Oct 2020 12:30'	System	12 Oct 2020 19:30:39



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 5'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'None (0)'	System	13 Oct 2020 20:06:46

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered 'No (N)'	System	13 Oct 2020 20:06:46

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-13T13:06:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'de3a067a-d4ff-42f3-8ecc-f7f0d52c79e2'	System	13 Oct 2020 20:06:46
User entered '13 Oct 2020 13:06'	System	13 Oct 2020 20:06:46

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 6'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30



US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:36:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'None (0)'	System	14 Oct 2020 19:37:30

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:20', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered 'No (N)'	System	14 Oct 2020 19:37:30

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-14T12:37:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'c32e7830-2578-4020-b9ac-f8c618d2ec74'	System	14 Oct 2020 19:37:30
User entered '14 Oct 2020 12:37'	System	14 Oct 2020 19:37:30

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 20:16:54



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	09 Oct 2020 20:16:54
User entered 'Day 7'	System	09 Oct 2020 20:16:54

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:06', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'None (0)'	System	16 Oct 2020 00:02:40

US3792094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered 'No (N)'	System	16 Oct 2020 00:02:40



**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-10-15T17:02:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5841fae0-53d6-4e9e-8dda-58228ea764b0'	System	16 Oct 2020 00:02:40
User entered '15 Oct 2020 17:02'	System	16 Oct 2020 00:02:40

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 20:16:54

**US3792094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	19 Oct 2020 20:14:28

**US3792094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '19 Oct 2020'	Ann Marie Milliken	19 Oct 2020 20:14:28

**US3792094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:28

US3792094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:28

**US3792094**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	19 Oct 2020 20:14:34



**US3792094**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	19 Oct 2020 20:14:34

**US3792094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	23 Oct 2020 20:21:35

**US3792094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '23 Oct 2020'	Ann Marie Milliken	23 Oct 2020 20:21:35

**US3792094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	23 Oct 2020 20:21:35

US3792094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	23 Oct 2020 20:21:35

**US3792094**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	23 Oct 2020 20:21:41

**US3792094**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	23 Oct 2020 20:21:41

**US3792094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	30 Oct 2020 19:05:32



**US3792094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '30 Oct 2020'	Ann Marie Milliken	30 Oct 2020 19:05:32

**US3792094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	30 Oct 2020 19:05:32

**US3792094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Ann Marie Milliken (b) (4)	30 Oct 2020 19:05:32

**US3792094**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	30 Oct 2020 19:05:37
	(b) (4)	

**US3792094**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	30 Oct 2020 19:05:37

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:12:11

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:12:11

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	06 Nov 2020 20:12:11



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'VISIT2'	System	06 Nov 2020 20:12:11

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Pre-Dose (PREDOSE)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '11:39'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '6 Nov 2020 11:39'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '98.2' F	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '65'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'bpm'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '14'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'breaths/min'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '130'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '80'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Post-Dose (POSTDOSE)'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '13:09'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '6 Nov 2020 13:09'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '98.2' F	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '64'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'bpm'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '16'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

US3792094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'breaths/min'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '107'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '79'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:08



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	13 Nov 2020 18:38:08

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:31:31

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:31:31

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'MRNA-1273 OR PLACEBO'	System	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '12:19'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '6 Nov 2020 12:19'	System	06 Nov 2020 20:11:52

US3792094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4)	06 Nov 2020 20:11:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'ONCE'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'INTRAMUSCULAR'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:35

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:35

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '11:43'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:35



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '6 Nov 2020 11:43'	System	13 Nov 2020 18:38:35

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:52:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '6 Nov 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '11:50'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '6 Nov 2020 11:50'	System	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52



**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered empty.	System	13 Nov 2020 18:38:52

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:12:22

**US3792094**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '1'	System	06 Nov 2020 20:12:22

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:12:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered 'Yes (Y)'	System	06 Nov 2020 20:13:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:12:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered '98.2'	System	06 Nov 2020 20:13:09

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:12:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered 'No (N)'	System	06 Nov 2020 20:13:09



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '4c90c9b0-ad72-4122-a238-c0451058d3f3'	System	06 Nov 2020 20:13:09
User entered '06 Nov 2020 13:13'	System	06 Nov 2020 20:13:09

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 12:39'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 15:09'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, after vaccination (at home)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:09:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered 'Yes (Y)'	System	07 Nov 2020 01:10:51

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:10:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered '95.4'	System	07 Nov 2020 01:10:51

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:10:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered 'No (N)'	System	07 Nov 2020 01:10:51

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:10:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e882e192-ca5e-4f6f-8ef0-fac2fd21a446'	System	07 Nov 2020 01:10:51
User entered '06 Nov 2020 18:10'	System	07 Nov 2020 01:10:51



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 16:04'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '07 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 2'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered 'Yes (Y)'	System	08 Nov 2020 04:09:55

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:44', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e' User entered '98.5'	System	08 Nov 2020 04:09:55
	System	08 Nov 2020 04:09:55

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered 'No (N)'	System	08 Nov 2020 04:09:55

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:09:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '653d2312-020a-4e08-9b31-9e455b317f6e'	System	08 Nov 2020 04:09:55
User entered '07 Nov 2020 21:09'	System	08 Nov 2020 04:09:55

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 20:11:52



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 3'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:54:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered 'Yes (Y)'	System	09 Nov 2020 02:55:58

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:55:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered '98.0'	System	09 Nov 2020 02:55:58

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:55:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered 'No (N)'	System	09 Nov 2020 02:55:58

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:55:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8ee65e23-24d1-43fd-ab5b-446211b45a29'	System	09 Nov 2020 02:55:58
User entered '08 Nov 2020 19:55'	System	09 Nov 2020 02:55:58

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 20:11:52



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 4'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:49:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered 'Yes (Y)'	System	10 Nov 2020 06:50:05

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:49:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c' User entered '97.5'	System	10 Nov 2020 06:50:05
	System	10 Nov 2020 06:50:05

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:49:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered 'No (N)'	System	10 Nov 2020 06:50:05

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '24113f57-ddd0-4e2b-9705-37eb201c240c'	System	10 Nov 2020 06:50:05
User entered '09 Nov 2020 23:50'	System	10 Nov 2020 06:50:05

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 5'	System	06 Nov 2020 20:11:52



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:56:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered 'Yes (Y)'	System	11 Nov 2020 06:57:56

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:42', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered '96.8'	System	11 Nov 2020 06:57:56

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:46', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered 'No (N)'	System	11 Nov 2020 06:57:56

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:52', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '7724e20d-4650-4cef-b0c3-16bcf394faf0'	System	11 Nov 2020 06:57:56
User entered '10 Nov 2020 23:57'	System	11 Nov 2020 06:57:56

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 6'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T20:59:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered 'Yes (Y)'	System	12 Nov 2020 04:00:19



US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered '98.2'	System	12 Nov 2020 04:00:19

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:06', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered 'No (N)'	System	12 Nov 2020 04:00:19

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '47800afc-35a8-4b5e-b5b4-1f1abb89d726'	System	12 Nov 2020 04:00:19
User entered '11 Nov 2020 21:00'	System	12 Nov 2020 04:00:19

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 7'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:38:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered 'Yes (Y)'	System	13 Nov 2020 02:39:18

US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:06', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered '95.4'	System	13 Nov 2020 02:39:18



US3792094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered 'No (N)'	System	13 Nov 2020 02:39:18

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'fb2fe3c2-4d42-426a-a135-32dc69d40460'	System	13 Nov 2020 02:39:18
User entered '12 Nov 2020 19:39'	System	13 Nov 2020 02:39:18

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'None (1)'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'No (N)'	System	06 Nov 2020 20:13:57

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:38', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'No (N)'	System	06 Nov 2020 20:13:57



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered 'None (1)'	System	06 Nov 2020 20:13:57

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '79fe30e9-644c-4092-9565-94a32fd0c9b6'	System	06 Nov 2020 20:13:57
User entered '06 Nov 2020 13:13'	System	06 Nov 2020 20:13:57

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 12:39'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 15:09'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, after vaccination (at home)'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'None (1)'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'No (N)'	System	07 Nov 2020 01:11:33

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'No (N)'	System	07 Nov 2020 01:11:33



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered 'None (1)'	System	07 Nov 2020 01:11:33

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:11:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ea99734e-22f5-468e-9042-f68dde4da310'	System	07 Nov 2020 01:11:33
User entered '06 Nov 2020 18:11'	System	07 Nov 2020 01:11:33

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 16:04'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '07 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 2'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'None (1)'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'No (N)'	System	08 Nov 2020 04:10:26

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'No (N)'	System	08 Nov 2020 04:10:26



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered 'None (1)'	System	08 Nov 2020 04:10:26

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0d5cb598-1a31-47c4-b754-e05c93349622'	System	08 Nov 2020 04:10:26
User entered '07 Nov 2020 21:10'	System	08 Nov 2020 04:10:26

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 3'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'None (1)'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'No (N)'	System	09 Nov 2020 02:56:24

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'No (N)'	System	09 Nov 2020 02:56:24



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:14', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered 'None (1)'	System	09 Nov 2020 02:56:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b0bc647b-b67f-4f91-8536-958b9895f66f'	System	09 Nov 2020 02:56:24
User entered '08 Nov 2020 19:56'	System	09 Nov 2020 02:56:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 4'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'None (1)'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'No (N)'	System	10 Nov 2020 06:50:28

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'No (N)'	System	10 Nov 2020 06:50:28



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:18', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered 'None (1)'	System	10 Nov 2020 06:50:28

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:22', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f33b3fc-df88-43fe-af7e-c38b163c85ec'	System	10 Nov 2020 06:50:28
User entered '09 Nov 2020 23:50'	System	10 Nov 2020 06:50:28

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 5'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:57:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'None (1)'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'No (N)'	System	11 Nov 2020 06:58:13

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'No (N)'	System	11 Nov 2020 06:58:13



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered 'None (1)'	System	11 Nov 2020 06:58:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '1f14154c-0936-4992-8300-f738a133f4f7'	System	11 Nov 2020 06:58:13
User entered '10 Nov 2020 23:58'	System	11 Nov 2020 06:58:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 6'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'None (1)'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'No (N)'	System	12 Nov 2020 04:00:45

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'No (N)'	System	12 Nov 2020 04:00:45



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered 'None (1)'	System	12 Nov 2020 04:00:45

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '42718bbf-97b1-423d-bd7a-7e9e53d27cf0'	System	12 Nov 2020 04:00:45
User entered '11 Nov 2020 21:00'	System	12 Nov 2020 04:00:45

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 7'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'None (1)'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'No (N)'	System	13 Nov 2020 02:39:43

US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'No (N)'	System	13 Nov 2020 02:39:43



US3792094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered 'None (1)'	System	13 Nov 2020 02:39:43

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '02d93d7e-ad1a-41d3-8617-fb21a02d2ba3'	System	13 Nov 2020 02:39:43
User entered '12 Nov 2020 19:39'	System	13 Nov 2020 02:39:43

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:13:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24



US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'None (0)'	System	06 Nov 2020 20:14:24

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered 'No (N)'	System	06 Nov 2020 20:14:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T13:14:20', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f454887d-2f61-4025-9862-bf848f2819cb'	System	06 Nov 2020 20:14:24
User entered '06 Nov 2020 13:14'	System	06 Nov 2020 20:14:24

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 12:39'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 15:09'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 1, after vaccination (at home)'	System	06 Nov 2020 20:11:52



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:41', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'None (0)'	System	07 Nov 2020 01:13:02

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered 'No (N)'	System	07 Nov 2020 01:13:02

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-06T18:12:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '8165700f-b3e4-405c-a862-f198d9d502e4'	System	07 Nov 2020 01:13:02
User entered '06 Nov 2020 18:12'	System	07 Nov 2020 01:13:02



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '06 Nov 2020 16:04'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '07 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 2'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'None (0)'	System	08 Nov 2020 04:11:08

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:10:54', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered 'No (N)'	System	08 Nov 2020 04:11:08

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-07T21:11:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '93f0efd1-9bb0-4923-aa7f-36a2fef00b68'	System	08 Nov 2020 04:11:08
User entered '07 Nov 2020 21:11'	System	08 Nov 2020 04:11:08

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '07 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '08 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 3'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:24', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54



US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:29', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:31', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:34', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:36', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'None (0)'	System	09 Nov 2020 02:56:54

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered 'No (N)'	System	09 Nov 2020 02:56:54

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-08T19:56:49', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2f17c792-7c78-4541-b047-f62350554d8e'	System	09 Nov 2020 02:56:54
User entered '08 Nov 2020 19:56'	System	09 Nov 2020 02:56:54

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '08 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Nov 2020 11:59'	System	06 Nov 2020 20:11:52



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 4'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:26', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:37', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:39', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'None (0)'	System	10 Nov 2020 06:50:59

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered 'No (N)'	System	10 Nov 2020 06:50:59



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-09T23:50:55', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '148fb8e5-5c9c-4e1f-bc58-b13ba10fde11'	System	10 Nov 2020 06:50:59
User entered '09 Nov 2020 23:50'	System	10 Nov 2020 06:50:59

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '09 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 5'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:13', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:23', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'None (0)'	System	11 Nov 2020 06:58:34

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:28', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered 'No (N)'	System	11 Nov 2020 06:58:34

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-10T23:58:32', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '09bfa454-840c-4728-8f46-fbb8d2a59315'	System	11 Nov 2020 06:58:34
User entered '10 Nov 2020 23:58'	System	11 Nov 2020 06:58:34

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '10 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 6'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:00:59', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'None (0)'	System	12 Nov 2020 04:01:13

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:01:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered 'No (N)'	System	12 Nov 2020 04:01:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-11T21:01:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b47d646e-2a19-4eb1-9175-3f5bfe80fcc2'	System	12 Nov 2020 04:01:13
User entered '11 Nov 2020 21:01'	System	12 Nov 2020 04:01:13

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '11 Nov 2020 12:00'	System	06 Nov 2020 20:11:52



**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
Data entry locked.	System	06 Nov 2020 20:11:52
User entered 'Day 7'	System	06 Nov 2020 20:11:52

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:48', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:51', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:39:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'None (0)'	System	13 Nov 2020 02:40:12



US3792094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:52:10

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:40:02', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered 'No (N)'	System	13 Nov 2020 02:40:12

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-11-12T19:40:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f84a57cd-394d-43ad-9f39-48ea46bcc20d'	System	13 Nov 2020 02:40:12
User entered '12 Nov 2020 19:40'	System	13 Nov 2020 02:40:12

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '12 Nov 2020 12:00'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:52:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:38:21
User entered '13 Nov 2020 11:59'	System	06 Nov 2020 20:11:52

**US3792094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	13 Nov 2020 18:51:10

**US3792094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '13 Nov 2020'	Ann Marie Milliken	13 Nov 2020 18:51:10

**US3792094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	13 Nov 2020 18:51:10

US3792094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Ann Marie Milliken (b) (4)	13 Nov 2020 18:51:10



**US3792094**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	13 Nov 2020 18:51:16

**US3792094**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	13 Nov 2020 18:51:16

**US3792094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	20 Nov 2020 18:13:11

**US3792094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '20 Nov 2020'	Ann Marie Milliken	20 Nov 2020 18:13:11

**US3792094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	20 Nov 2020 18:13:11

US3792094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	20 Nov 2020 18:13:11

**US3792094**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	20 Nov 2020 18:14:07

**US3792094**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	20 Nov 2020 18:14:07



**US3792094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	01 Dec 2020 22:18:31

**US3792094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '30 Nov 2020'	Ann Marie Milliken (b) (4)	01 Dec 2020 22:18:31

**US3792094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	01 Dec 2020 22:18:31

US3792094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:10

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Ann Marie Milliken (b) (4)	01 Dec 2020 22:18:31

**US3792094**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	01 Dec 2020 22:18:37

**US3792094**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	01 Dec 2020 22:18:37

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Dec 2020 18:09:56

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '4 Dec 2020'	Norma Frederick (b) (4)	04 Dec 2020 18:09:56



**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	04 Dec 2020 18:09:56

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'VISIT3'	System	04 Dec 2020 18:09:56

US3792094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '4 Dec 2020'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '11:13'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '4 Dec 2020 11:13'	System	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '98.2' F	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55



**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '62'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'bpm'	System	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '14'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'breaths/min'	System	04 Dec 2020 18:42:55

US3792094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '138'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	04 Dec 2020 18:42:55

US3792094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '83'	Norma Frederick (b) (4)	04 Dec 2020 18:42:55



**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'mmHg'	System	04 Dec 2020 18:42:55

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'No (N)'	Norma Frederick (b) (4)	04 Dec 2020 18:10:17

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered empty.	Norma Frederick (b) (4)	04 Dec 2020 18:10:17

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Dec 2020 18:43:12

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '4 Dec 2020'	Norma Frederick (b) (4)	04 Dec 2020 18:43:12

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered '11:17'	Norma Frederick (b) (4)	04 Dec 2020 18:43:12



**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered '4 Dec 2020 11:17'	System	04 Dec 2020 18:43:12

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:52
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Dec 2020 18:10:25

**US3792094**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	04 Dec 2020 18:10:25

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2020-12-08T22:05:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a2368649-16c4-46a2-9043-eb779e7334a3'	System	09 Dec 2020 05:06:16
User entered 'No (N)'	System	09 Dec 2020 05:06:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2020-12-08T22:05:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a2368649-16c4-46a2-9043-eb779e7334a3'	System	09 Dec 2020 05:06:16
User entered 'No (N)'	System	09 Dec 2020 05:06:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-12-08T22:06:12', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a2368649-16c4-46a2-9043-eb779e7334a3'	System	09 Dec 2020 05:06:16
User entered '08 Dec 2020 22:06:12'	System	09 Dec 2020 05:06:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2020-12-15T13:47:45', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5797c1b0-0807-490f-bbbf-4bfcc4e47eea'	System	15 Dec 2020 20:48:24
User entered 'No (N)'	System	15 Dec 2020 20:48:24

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2020-12-15T13:47:56', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5797c1b0-0807-490f-bbbf-4bfcc4e47eea'	System	15 Dec 2020 20:48:24
User entered 'No (N)'	System	15 Dec 2020 20:48:24

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-12-15T13:48:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5797c1b0-0807-490f-bbbf-4bfcc4e47eea'	System	15 Dec 2020 20:48:24
User entered '15 Dec 2020 13:48:19'	System	15 Dec 2020 20:48:24

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2020-12-20T04:49:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a3a5706d-f385-4257-91c6-3cd95a50dbcd'	System	20 Dec 2020 11:50:00
User entered 'No (N)'	System	20 Dec 2020 11:50:00

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2020-12-20T04:49:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a3a5706d-f385-4257-91c6-3cd95a50dbcd'	System	20 Dec 2020 11:50:00
User entered 'No (N)'	System	20 Dec 2020 11:50:00

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-12-20T04:49:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a3a5706d-f385-4257-91c6-3cd95a50dbcd'	System	20 Dec 2020 11:50:00
User entered '20 Dec 2020 04:49:57'	System	20 Dec 2020 11:50:00

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2020-12-28T11:32:10', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ab765837-1f4a-471f-8bb7-f11ea885afd1'	System	28 Dec 2020 18:32:22
User entered 'No (N)'	System	28 Dec 2020 18:32:22

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2020-12-28T11:32:15', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ab765837-1f4a-471f-8bb7-f11ea885afd1'	System	28 Dec 2020 18:32:22
User entered 'No (N)'	System	28 Dec 2020 18:32:22



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2020-12-28T11:32:19', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'ab765837-1f4a-471f-8bb7-f11ea885afd1' User entered '28 Dec 2020 11:32:19'	System	28 Dec 2020 18:32:22
	System	28 Dec 2020 18:32:22

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-01-03T06:43:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a02064fb-92f4-431b-91cf-f19015dc17'	System	03 Jan 2021 13:44:15
User entered 'No (N)'	System	03 Jan 2021 13:44:15

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-01-03T06:44:04', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a02064fb-92f4-431b-91cf-f19015dc17'	System	03 Jan 2021 13:44:15
User entered 'No (N)'	System	03 Jan 2021 13:44:15

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-01-03T06:44:09', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a02064fb-92f4-431b-91cf-f19015dc17'	System	03 Jan 2021 13:44:15
User entered '03 Jan 2021 06:44:09'	System	03 Jan 2021 13:44:15

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-01-10T05:49:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cf97e9fe-4931-4b5a-a004-66c3057ccc33'	System	10 Jan 2021 12:49:17
User entered 'No (N)'	System	10 Jan 2021 12:49:17

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-01-10T05:49:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cf97e9fe-4931-4b5a-a004-66c3057ccc33'	System	10 Jan 2021 12:49:17
User entered 'No (N)'	System	10 Jan 2021 12:49:17

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-01-10T05:49:11', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'cf97e9fe-4931-4b5a-a004-66c3057ccc33'	System	10 Jan 2021 12:49:17
User entered '10 Jan 2021 05:49:11'	System	10 Jan 2021 12:49:17

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-01-17T15:13:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2be0d164-d3ef-4ee4-9692-4837299622cc'	System	17 Jan 2021 22:14:10
User entered 'No (N)'	System	17 Jan 2021 22:14:10

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-01-17T15:13:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2be0d164-d3ef-4ee4-9692-4837299622cc'	System	17 Jan 2021 22:14:10
User entered 'No (N)'	System	17 Jan 2021 22:14:10

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-01-17T15:14:05', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '2be0d164-d3ef-4ee4-9692-4837299622cc'	System	17 Jan 2021 22:14:10
User entered '17 Jan 2021 15:14:05'	System	17 Jan 2021 22:14:10

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-01-24T20:38:43', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f883fcf8-a4ca-4d4b-b583-06ff06769c3c'	System	25 Jan 2021 03:39:08
User entered 'No (N)'	System	25 Jan 2021 03:39:08

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-01-24T20:38:57', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f883fcf8-a4ca-4d4b-b583-06ff06769c3c'	System	25 Jan 2021 03:39:08
User entered 'No (N)'	System	25 Jan 2021 03:39:08



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-01-24T20:39:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f883fcf8-a4ca-4d4b-b583-06ff06769c3c'	System	25 Jan 2021 03:39:08
User entered '24 Jan 2021 20:39:03'	System	25 Jan 2021 03:39:08

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-02-01T14:21:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3c43ffa3-b4a1-4184-9bc5-ba3896f77cfe'	System	01 Feb 2021 21:22:16
User entered 'Yes (Y)'	System	01 Feb 2021 21:22:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-02-01T14:21:30', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3c43ffa3-b4a1-4184-9bc5-ba3896f77cfe'	System	01 Feb 2021 21:22:16
User entered 'No (N)'	System	01 Feb 2021 21:22:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-01T14:21:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3c43ffa3-b4a1-4184-9bc5-ba3896f77cfe'	System	01 Feb 2021 21:22:16
User entered 'No (N)'	System	01 Feb 2021 21:22:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-01T14:21:47', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3c43ffa3-b4a1-4184-9bc5-ba3896f77cfe'	System	01 Feb 2021 21:22:16
User entered 'Yes (Y)'	System	01 Feb 2021 21:22:16



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-01T14:21:58', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3c43ffa3-b4a1-4184-9bc5-ba3896f77cfe'	System	01 Feb 2021 21:22:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 21:22:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-01T14:22:03', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '3c43ffa3-b4a1-4184-9bc5-ba3896f77cfe'	System	01 Feb 2021 21:22:16
User entered '01 Feb 2021 14:22:03'	System	01 Feb 2021 21:22:16

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-02-07T03:13:40', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '90bbef55-e7ff-4379-810a-b109cae903e1'	System	07 Feb 2021 10:14:03
User entered 'No (N)'	System	07 Feb 2021 10:14:03

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-02-07T03:13:53', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '90bbef55-e7ff-4379-810a-b109cae903e1'	System	07 Feb 2021 10:14:03
User entered 'No (N)'	System	07 Feb 2021 10:14:03

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-07T03:14:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '90bbef55-e7ff-4379-810a-b109cae903e1'	System	07 Feb 2021 10:14:03
User entered '07 Feb 2021 03:14:00'	System	07 Feb 2021 10:14:03



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-02-15T20:31:21', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a43f8edf-e11e-4e5f-a8f7-4f3642c27f42'	System	16 Feb 2021 03:31:38
User entered 'No (N)'	System	16 Feb 2021 03:31:38

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-02-15T20:31:25', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a43f8edf-e11e-4e5f-a8f7-4f3642c27f42'	System	16 Feb 2021 03:31:38
User entered 'No (N)'	System	16 Feb 2021 03:31:38

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-15T20:31:35', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'a43f8edf-e11e-4e5f-a8f7-4f3642c27f42'	System	16 Feb 2021 03:31:38
User entered '15 Feb 2021 20:31:35'	System	16 Feb 2021 03:31:38

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-02-21T05:19:07', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e4171378-8d23-48b3-8bc3-3d139090e354'	System	21 Feb 2021 12:19:30
User entered 'No (N)'	System	21 Feb 2021 12:19:30

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-02-21T05:19:16', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e4171378-8d23-48b3-8bc3-3d139090e354'	System	21 Feb 2021 12:19:30
User entered 'No (N)'	System	21 Feb 2021 12:19:30

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-02-21T05:19:27', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'e4171378-8d23-48b3-8bc3-3d139090e354'	System	21 Feb 2021 12:19:30
User entered '21 Feb 2021 05:19:27'	System	21 Feb 2021 12:19:30

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-03-01T19:53:18-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f9b98e0c-028b-4b4a-874f-1b1ed2f195c4'	System	02 Mar 2021 02:54:45
User entered 'No (N)'	System	02 Mar 2021 02:54:45



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-03-01T19:53:34-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f9b98e0c-028b-4b4a-874f-1b1ed2f195c4'	System	02 Mar 2021 02:54:45
User entered 'No (N)'	System	02 Mar 2021 02:54:45

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-01T19:53:40-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f9b98e0c-028b-4b4a-874f-1b1ed2f195c4'	System	02 Mar 2021 02:54:45
User entered '01 Mar 2021 19:53:40'	System	02 Mar 2021 02:54:45

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-03-07T09:50:30-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b552b1ff-0a57-488c-be5e-77a04e7696e3'	System	07 Mar 2021 16:50:50
User entered 'No (N)'	System	07 Mar 2021 16:50:50

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-03-07T09:50:43-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b552b1ff-0a57-488c-be5e-77a04e7696e3'	System	07 Mar 2021 16:50:50
User entered 'No (N)'	System	07 Mar 2021 16:50:50

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-07T09:50:48-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b552b1ff-0a57-488c-be5e-77a04e7696e3'	System	07 Mar 2021 16:50:50
User entered '07 Mar 2021 09:50:48'	System	07 Mar 2021 16:50:50



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-03-16T17:33:56-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b96d389a-a996-4125-973d-2f69ae30b967'	System	17 Mar 2021 00:34:11
User entered 'No (N)'	System	17 Mar 2021 00:34:11

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-03-16T17:34:02-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b96d389a-a996-4125-973d-2f69ae30b967'	System	17 Mar 2021 00:34:11
User entered 'No (N)'	System	17 Mar 2021 00:34:11

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-16T17:34:07-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'b96d389a-a996-4125-973d-2f69ae30b967'	System	17 Mar 2021 00:34:11
User entered '16 Mar 2021 17:34:07'	System	17 Mar 2021 00:34:11

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-03-22T02:00:43-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5706d1b1-b417-4608-a1a1-efd3355109cd'	System	22 Mar 2021 09:01:01
User entered 'No (N)'	System	22 Mar 2021 09:01:01

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-03-22T02:00:51-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5706d1b1-b417-4608-a1a1-efd3355109cd'	System	22 Mar 2021 09:01:01
User entered 'No (N)'	System	22 Mar 2021 09:01:01

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-22T02:00:57-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '5706d1b1-b417-4608-a1a1-efd3355109cd' User entered '22 Mar 2021 02:00:57'	System	22 Mar 2021 09:01:01
	System	22 Mar 2021 09:01:01

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-03-29T23:33:39-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'bc1baefc-aaf4-452a-9612-95d1f1fb05a8'	System	30 Mar 2021 06:33:58
User entered 'No (N)'	System	30 Mar 2021 06:33:58



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-03-29T23:33:47-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'bc1baefc-aaf4-452a-9612-95d1f1fb05a8'	System	30 Mar 2021 06:33:58
User entered 'No (N)'	System	30 Mar 2021 06:33:58

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-29T23:33:51-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'bc1baefc-aaf4-452a-9612-95d1f1fb05a8' User entered '29 Mar 2021 23:33:51'	System	30 Mar 2021 06:33:58

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-04-04T12:47:17-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0aae8d2c-1c25-48f5-a10c-bb364cc7eec3'	System	04 Apr 2021 19:47:31
User entered 'No (N)'	System	04 Apr 2021 19:47:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-04-04T12:47:21-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0aae8d2c-1c25-48f5-a10c-bb364cc7eec3'	System	04 Apr 2021 19:47:31
User entered 'No (N)'	System	04 Apr 2021 19:47:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-04-04T12:47:25-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0aae8d2c-1c25-48f5-a10c-bb364cc7eec3'	System	04 Apr 2021 19:47:31
User entered '04 Apr 2021 12:47:25'	System	04 Apr 2021 19:47:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-04-11T14:14:23-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6b27c23f-983b-425a-8852-e9b1361dda9c'	System	11 Apr 2021 21:14:38
User entered 'No (N)'	System	11 Apr 2021 21:14:38

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-04-11T14:14:27-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6b27c23f-983b-425a-8852-e9b1361dda9c'	System	11 Apr 2021 21:14:38
User entered 'No (N)'	System	11 Apr 2021 21:14:38

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-04-11T14:14:31-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '6b27c23f-983b-425a-8852-e9b1361dda9c'	System	11 Apr 2021 21:14:38
User entered '11 Apr 2021 14:14:31'	System	11 Apr 2021 21:14:38

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-04-18T02:04:20-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '56e0fdb8-11ab-4ff0-94fe-c0c4bc29f13a' User entered 'No (N)'	System	18 Apr 2021 09:04:35
	System	18 Apr 2021 09:04:35

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-04-18T02:04:23-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '56e0fdb8-11ab-4ff0-94fe-c0c4bc29f13a' User entered 'No (N)'	System	18 Apr 2021 09:04:35

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-04-18T02:04:27-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '56e0fdb8-11ab-4ff0-94fe-c0c4bc29f13a' User entered '18 Apr 2021 02:04:27'	System	18 Apr 2021 09:04:35
	System	18 Apr 2021 09:04:35

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-04-26T12:03:37-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0880b2fb-8499-4bf9-87e9-ee18fa0e25f9' User entered 'No (N)'	System	26 Apr 2021 19:03:48
	System	26 Apr 2021 19:03:48



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-04-26T12:03:39-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0880b2fb-8499-4bf9-87e9-ee18fa0e25f9' User entered 'No (N)'	System	26 Apr 2021 19:03:48

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-04-26T12:03:43-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '0880b2fb-8499-4bf9-87e9-ee18fa0e25f9'	System	26 Apr 2021 19:03:48
User entered '26 Apr 2021 12:03:43'	System	26 Apr 2021 19:03:48

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[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 (88c81b8af040f89c)', Time: '2021-05-02T04:27:56-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f7bb200c-1561-4933-9c0f-0acc466b473a'	System	02 May 2021 11:28:11
User entered 'No (N)'	System	02 May 2021 11:28:11

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

Have you been exposed to someone with 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 (88c81b8af040f89c)', Time: '2021-05-02T04:28:01-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f7bb200c-1561-4933-9c0f-0acc466b473a'	System	02 May 2021 11:28:11
User entered 'No (N)'	System	02 May 2021 11:28:11

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-05-02T04:28:05-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: 'f7bb200c-1561-4933-9c0f-0acc466b473a'	System	02 May 2021 11:28:11
User entered '02 May 2021 04:28:05'	System	02 May 2021 11:28:11



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:14:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:14:31



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:14:31



**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:14:31

**US3792094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:52:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:14:31
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:14:31

US3792094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:52:10

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)	30 Apr 2021 22:02:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-01T19:52:54-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '31e113e9-bc7a-4f94-9420-c25d84b5c3b9' User entered 'No (N)'	System	02 Mar 2021 02:54:19
	System	02 Mar 2021 02:54:19

**US3792094**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:02:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (88c81b8af040f89c)', Time: '2021-03-01T19:53:03-07:00', User OID: 'PatientReportedOutcome (US3792094)', ODM File OID: '31e113e9-bc7a-4f94-9420-c25d84b5c3b9' User entered '01 Mar 2021 19:53:03'	System	02 Mar 2021 02:54:19
	System	02 Mar 2021 02:54:19



**US3792094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	14 Jan 2021 20:28:22

**US3792094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '4 Jan 2021'	Ann Marie Milliken	14 Jan 2021 20:28:22

**US3792094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	14 Jan 2021 20:28:22

**US3792094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Ann Marie Milliken (b) (4)	14 Jan 2021 20:28:22

**US3792094**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	14 Jan 2021 20:28:27

**US3792094**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 12:47:13
User entered 'I'	System	14 Jan 2021 20:28:27

**US3792094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	19 Feb 2021 19:28:02

**US3792094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '4 Feb 2021'	Ann Marie Milliken	19 Feb 2021 19:28:02



**US3792094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	19 Feb 2021 19:28:02

**US3792094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Ann Marie Milliken (b) (4)	19 Feb 2021 19:28:02

**US3792094**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Ann Marie Milliken	19 Feb 2021 19:28:07

**US3792094**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User entered '1'	System	19 Feb 2021 19:28:07

**US3792094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 17:35:58

**US3792094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '5 Mar 2021'	Ann Marie Milliken (b) (4)	05 Mar 2021 17:35:58

**US3792094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 17:35:58

**US3792094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 17:35:58



**US3792094**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Mar 2021 17:36:04

**US3792094**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:28:37
User entered 'I'	System	05 Mar 2021 17:36:04

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:37
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:58:58

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:37
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered '5 Apr 2021'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:58:58

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:37
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:58:58

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:37
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:58:58

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:37
User signature succeeded.	Abram Burgher (b) (4)	08 Apr 2021 22:51:03
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	07 Apr 2021 16:59:03

**US3792094**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:37
User entered 'I'	System	07 Apr 2021 16:59:03



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 22:27:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 22:27:42
User entered '2 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	02 Feb 2021 22:27:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 20:47:58
User entered empty.	System	02 Feb 2021 20:47:58
	Norma Frederick (b) (4)	02 Feb 2021 20:47:58
	(b) (4)	

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 22:27:42
User entered '14:00' reason for change: Data Entry Error	Norma Frederick (b) (4)	02 Feb 2021 22:27:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Feb 2021 20:47:58
	Norma Frederick (b) (4)	02 Feb 2021 20:47:58
	(b) (4)	

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:52:10**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:41
User entered '2 Feb 2021 14:00'	System	02 Feb 2021 22:27:42
User entered empty.	System	02 Feb 2021 20:47:58

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 22:27:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 22:27:42
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Norma Frederick (b) (4)	02 Feb 2021 22:27:42
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 20:47:58
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 20:47:58

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:41
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 22:27:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 22:27:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	02 Feb 2021 22:27:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 20:47:58
User entered empty.	System	02 Feb 2021 20:47:58
	Norma Frederick (b) (4)	02 Feb 2021 20:47:58
	(b) (4)	

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 1 (Day 1)'	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '29 Jan 2021'	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'I'	Norma Frederick (b) (4)	02 Feb 2021 22:28:27



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered empty.	System	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:28:27

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 2 (Day 2)'	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '30 Jan 2021'	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'I'	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered empty.	System	02 Feb 2021 22:29:02



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:29:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 3 (Day 3)'	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '1 Feb 2021'	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'I'	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered empty.	System	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:30:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 4 (Day 4)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '2 Feb 2021'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered missing code ND - Not Done.	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.9' F	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Moderate (Moderate)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Norma Frederick (b) (4)	02 Feb 2021 22:32:01

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 22:32:01

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 5 (Day 5)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '3 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '99'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.1' F	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Mild (Mild)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	03 Feb 2021 22:04:06

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 6 (Day 6)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '4 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	05 Feb 2021 22:21:49



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.2' F	Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Mild (Mild)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:21:49

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 7 (Day 7)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '5 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '97.0' F	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Mild (Mild)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	05 Feb 2021 22:22:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 8 (Day 8)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52



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Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '6 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '99'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	10 Feb 2021 21:42:52

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Folder: Covid-19 Assessment 02 Feb 2021

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.2' F	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Mild (Mild)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52



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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:42:52

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 9 (Day 9)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '7 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '97.6' F	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Mild (Mild)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:45:42

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 10 (Day 10)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '8 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	10 Feb 2021 21:46:47



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '97.6' F	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:46:47

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 11 (Day 11)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '9 Feb 2021'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '97.6' F	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:47:50

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Day 12 (Day 12)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '10 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '0'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '99'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.4' F	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	10 Feb 2021 21:49:37

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Day 13 (Day 13)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '11 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

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**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '0'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '99'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	26 Feb 2021 16:54:11

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '98.7' F	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11



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Folder: Covid-19 Assessment 02 Feb 2021

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Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:54:11

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Day 14 (Day 14)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '12 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '0'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '98'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	26 Feb 2021 16:55:02



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '97.6' F	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:55:02

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Day 15 (Day 15)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '13 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '0'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '99'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	26 Feb 2021 16:56:08

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '97.8' F	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken	26 Feb 2021 16:56:08



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08



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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:08

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Day 16 (Day 16)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '14 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '0'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '99'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '97.6' F	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:56:57

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Day 17 (Day 17)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '15 Feb 2021'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '0'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51



**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '98'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User entered '%'	System	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '98.2' F	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken	26 Feb 2021 16:57:51

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: Symptom Log (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	(b) (4) Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:52:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:38:50
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'None (None)'	Ann Marie Milliken (b) (4)	26 Feb 2021 16:57:51

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered '2 Feb 2021'	Norma Frederick (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered 'No (N)'	Norma Frederick (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
Query 'Per GCL Lab Reconciliation: Swab: In Preclarus report, for the subject US3792094 Sample Collection date is recorded as 02FEB2021 under Illness Visit in PPD central lab, with accession number "1F657668808" and Requisition kit id "1F602266346". however same missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Apr 2021 14:48:00
User opened query 'Per GCL Lab Reconciliation: Swab: In Preclarus report, for the subject US3792094 Sample Collection date is recorded as 02FEB2021 under Illness Visit in PPD central lab, with accession number "1F657668808" and Requisition kit id "1F602266346". however same missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:45:32
User closed query 'Per GCL Lab Reconciliation: Swab: Per GCL, no Swab sample was received for the Covid-19 Assessment Visit on 30JAN2021. Please clarify if sample was shipped and provide the accession number and tracking details in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:45:32
Query 'Per GCL Lab Reconciliation: Swab: Per GCL, Norma Frederick no Swab sample was received for the Covid-19 Assessment Visit on 30JAN2021. Please clarify if sample was shipped and provide the accession number and tracking details in the query response box, as appropriate.' answered with 'SWAB RECEIVED AT LAB IN EXPIRED TUBE; NEVER TESTED SUBJECT RE SWABBED ON 2/25/2021' (Site from DM).	(b) (4) (b) (4)	10 Mar 2021 20:55:05
User entered '25 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	10 Mar 2021 20:53:53

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:10

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per GCL, no Swab sample was received for the Covid-19 Assessment Visit on 30JAN2021. Please clarify if sample was shipped and provide the accession number and tracking details in the query response box, as appropriate.' (Site from DM). User entered '30 Jan 2021'	(b) (4), (b) (6) (b) (4)	16 Feb 2021 17:32:25
	Norma Frederick (b) (4) (b) (4)	02 Feb 2021 22:33:16



US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered empty.	Norma Frederick (b) (4)	02 Feb 2021 22:33:16

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:10

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 25-Feb-2021 that is labelled as 'Unscheduled' in Preclarus, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Else Clarify, Thank you.	(b) (4), (b) (6)	29 Apr 2021 04:07:52
' (Site from DM).		
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 25-Feb-2021 that is labelled as 'Unscheduled' in Preclarus, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Else Clarify, Thank you.	Norma Frederick (b) (4)	20 Apr 2021 17:20:59
	(b) (4)	
' answered with 'site has no records of the outside swab. Only subject report ' (Site from DM).		

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:10

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Per CCG guidelines, if there are two swabs that are performed: one for the Central lab swab and the other at a local lab then data for both the swabs needs to be recorded. Since local lab swab is recorded on this COVID Diagnostic form and PPD Central lab also has a swab dated 25-Feb-2021 that is labelled as 'Unscheduled' in Preclarus, please confirm by updating the Central Lab Swab Data in the COVID Diagnostic Form by initiating a COVID-19 Assessment eCRF for the corresponding Date. Else Clarify, Thank you.  ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:10:45
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered 'Urgent care'	Norma Frederick (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:45:06
User entered 'Yes (Y)'	Norma Frederick (b) (4)	02 Feb 2021 22:33:16

**US3792094**

**Folder: Covid-19 Assessment 02 Feb 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:52:10**

**COVID-19 Positive (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:00
User entered '0'	System	02 Feb 2021 22:33:16

US3792094

Folder: Covid-19 Assessment 02 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:52:10

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:39:04
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	02 Feb 2021 20:29:00



**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 3 (Day 3)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '4 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 5 (Day 5)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '6 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 7 (Day 7)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20



**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '8 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 9 (Day 9)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '10 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 14 (Day 14)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

US3792094

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 17Feb2021 for Day 14 is recorded in EDC, however sample is reported with 15Feb2021 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 05:48:48
Query 'Per GCL Lab Recon: Saliva: Sample dated 17Feb2021 for Day 14 is recorded in EDC, however sample is reported with 15Feb2021 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. thank you.'	Norma Frederick (b) (4)	10 Mar 2021 20:59:38
answered with 'UPDATED ERROR' (Site from DM).	(b) (4)	
User entered '15 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	10 Mar 2021 20:59:13
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 17Feb2021 for Day 14 is recorded in EDC, however sample is reported with 15Feb2021 for Day 14 in PPD Central lab. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 06:39:16
User entered '17 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20
	(b) (4)	

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 21 (Day 21)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20



US3792094

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22FEB2021 for Day 21 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 07:54:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22FEB2021 for Day 21 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 22:43:12
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 22:41:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 22:41:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:41:15
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22FEB2021 for Day 21 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:40:27
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 02:26:26
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:26:26
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '22 Feb 2021' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 22:42:22
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 22:42:22
	Norma Frederick (b) (4)	26 Feb 2021 02:25:20
	(b) (4)	

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User accepted default value 'Day 28 (Day 28)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:03:57
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '5 Mar 2021' reason for change: Data Entry Error	(b) (4) Ann Marie Milliken	05 Mar 2021 21:07:48
User entered '24 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:25:20

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:21:54

US3792094

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06,08,10FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 08:26:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06,08,10FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'edc updated ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:36:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06,08,10FEB2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 03:55:55
User entered '2 Feb 2021'	Norma Frederick (b) (4) (b) (4)	02 Feb 2021 20:21:54

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Clinic (Clinic)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:21:54



**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:54
User entered 'SICKD1'	System	02 Feb 2021 20:21:54

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:16
	(b) (4)	

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '2 Feb 2021'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '12:42'	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:16
	(b) (4)	

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User entered '2 Feb 2021 12:42'	System	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered missing code ND - Not Done.	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:16
DataPoint set to visible.	(b) (4)	
	System	02 Feb 2021 20:21:54

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered missing code ND - Not Done.	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:16
DataPoint set to visible.	(b) (4)	
	System	02 Feb 2021 20:21:54

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.9' F	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:16



**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Oral (Oral)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:16
	(b) (4)	

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '62'	Norma Frederick (b) (4)	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User entered 'bpm'	System	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '16'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User entered 'breaths/min'	System	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '161'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User entered 'mmHg'	System	02 Feb 2021 20:23:16



**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '92'	Norma Frederick (b) (4)	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59
User entered 'mmHg'	System	02 Feb 2021 20:23:16

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:06:59

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:03
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:34
	(b) (4)	

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:03
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '2 Feb 2021'	(b) (4)	
	Norma Frederick (b) (4)	02 Feb 2021 20:23:34
	(b) (4)	

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:52:10**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:44

**US3792094**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:08
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '2 Feb 2021'	(b) (4) Norma Frederick (b) (4)	02 Feb 2021 20:23:44



**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:14
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:46:39

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:14
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '5 Mar 2021'	(b) (4)	
	Ann Marie Milliken	05 Mar 2021 20:46:39
	(b) (4)	

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:14
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Clinic (Clinic)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:46:39

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:14
User entered 'SICKD28'	System	05 Mar 2021 20:46:39

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	(b) (4)	
	Ann Marie Milliken	05 Mar 2021 20:47:52
	(b) (4)	

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '5 Mar 2021'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '10:03'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User entered '5 Mar 2021 10:03'	System	05 Mar 2021 20:47:52



US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered missing code ND - Not Done.	(b) (4) Ann Marie Milliken	05 Mar 2021 20:47:52
DataPoint set to visible.	(b) (4) System	05 Mar 2021 20:46:39

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered missing code ND - Not Done.	(b) (4) Ann Marie Milliken	05 Mar 2021 20:47:52
DataPoint set to visible.	(b) (4) System	05 Mar 2021 20:46:39

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 13:32:49
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Ann Marie Milliken (b) (4)	05 Mar 2021 20:48:05
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Mar 2021 20:47:52
User entered '94.7' F	Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Oral (Oral)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered empty.	(b) (4)	
	Ann Marie Milliken	05 Mar 2021 20:47:52
	(b) (4)	

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '69'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User entered 'bpm'	System	05 Mar 2021 20:47:52

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '16'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52



**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User entered 'breaths/min'	System	05 Mar 2021 20:47:52

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Per CDM : 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 DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:46:28
Query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 15:26:21
User opened query 'Per CDM : 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 DM).	(b) (4), (b) (6)	10 Mar 2021 14:22:39
User entered '171'	Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User entered 'mmHg'	System	05 Mar 2021 20:47:52

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '82'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:47:52

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18
User entered 'mmHg'	System	05 Mar 2021 20:47:52

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:18

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'No (N)'	(b) (4)	
	Ann Marie Milliken	05 Mar 2021 20:48:35
	(b) (4)	



**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:23
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:48:35

US3792094

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:52:10

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:49:10

**US3792094**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:52:10**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:07:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '5 Mar 2021'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 20:49:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:13

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 22:33:13

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:13

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 22:33:13

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:29:14

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
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 15:29:14

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27

US3792094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:55:28
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27
	(b) (4)	

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:55:28
User entered 'Placebo (Placebo)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27
	(b) (4)	

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 22:33:27



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered '1'	System	14 Jan 2021 22:33:27

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'I'	System	14 Jan 2021 22:33:27

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered empty.	System	14 Jan 2021 23:03:45
DataPoint set to visible.	System	14 Jan 2021 22:33:27

US3792094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:10

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered empty.	System	14 Jan 2021 23:03:45
DataPoint set to visible.	System	14 Jan 2021 22:33:27



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '12:20'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered '14 Jan 2021 12:20'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '97.6' F	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '71'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'bpm'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '16'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'breaths/min'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '134'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'mmHg'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '74'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'mmHg'	System	14 Jan 2021 23:03:45



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:52:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered empty.	System	14 Jan 2021 23:03:45
DataPoint set to visible.	System	14 Jan 2021 22:33:27

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:03:45

US3792094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '13:15'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered '14 Jan 2021 13:15'	System	14 Jan 2021 23:03:45



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '98.1' F	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '76'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'bpm'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '16'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'breaths/min'	System	14 Jan 2021 23:03:45

US3792094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '163'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'mmHg'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '76'	Norma Frederick (b) (4)	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'mmHg'	System	14 Jan 2021 23:03:45

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 22:37:21

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 22:37:21

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:05:10

US3792094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:05:10



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'mRNA-1273'	System	14 Jan 2021 23:05:10
DataPoint set to visible.	System	14 Jan 2021 22:33:27

US3792094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '12:45'	Norma Frederick (b) (4)	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered '14 Jan 2021 12:45'	System	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Right Arm (RIGHT ARM)'	Norma Frederick (b) (4)	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'ONCE'	System	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 23:05:10

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 22:35:06



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 22:35:06

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '12:23'	Norma Frederick (b) (4)	14 Jan 2021 22:35:06

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered '14 Jan 2021 12:23'	System	14 Jan 2021 22:35:06

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:52:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 22:35:23

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '14 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 22:35:23

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:52:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '12:28'	Norma Frederick (b) (4)	14 Jan 2021 22:35:23

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:52:10**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered '14 Jan 2021 12:28'	System	14 Jan 2021 22:35:23

**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 22:35:28



**US3792094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:21:28
User entered 'I'	System	14 Jan 2021 22:35:28

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered 'Yes (Y)'	Ann Marie Milliken	21 Jan 2021 17:59:38
	(b) (4)	

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '21 Jan 2021'	Ann Marie Milliken	21 Jan 2021 17:59:38
	(b) (4)	

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken	21 Jan 2021 17:59:38
	(b) (4)	

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered empty.	Ann Marie Milliken	21 Jan 2021 17:59:38
	(b) (4)	

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered 'Yes (Y)'	Ann Marie Milliken	21 Jan 2021 17:59:49
	(b) (4)	

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User entered 'I'	System	21 Jan 2021 17:59:49

**US3792094**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:24
User entered 'I'	System	21 Jan 2021 17:59:49
DataPoint set to visible.	System	21 Jan 2021 17:59:49



**US3792094**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:26:49

**US3792094**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '25 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:26:49

**US3792094**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Clinic (Clinic)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:26:49

**US3792094**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'OLD29'	System	26 Feb 2021 02:26:49

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '25 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '14:45'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 02:28:51
	(b) (4)	



**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered '25 Feb 2021 14:45'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '97.8' F	Norma Frederick (b) (4)	26 Feb 2021 02:28:51
	(b) (4)	

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Oral (Oral)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered empty.	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '58'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'bpm'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '16'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'breaths/min'	System	26 Feb 2021 02:28:51



**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '144'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'mmHg'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '76'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'mmHg'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '25 Feb 2021'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '15:47'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 02:28:51
	(b) (4)	



**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered '25 Feb 2021 15:47'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '97.3' F	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Oral (Oral)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered empty.	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '58'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'bpm'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '16'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'breaths/min'	System	26 Feb 2021 02:28:51



**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '150'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'mmHg'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '80'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'mmHg'	System	26 Feb 2021 02:28:51

**US3792094**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'No (N)'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 02:28:55
	(b) (4)	

**US3792094**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 02:28:55
	(b) (4)	

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:30:09

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered empty.	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 02:30:09
	(b) (4)	



**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

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)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:30:09

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'mRNA-1273'	System	26 Feb 2021 02:30:09
DataPoint set to visible.	System	21 Jan 2021 17:59:49

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '25 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:30:09

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered '15:15'	(b) (4)	
	Norma Frederick (b) (4)	26 Feb 2021 02:30:09
	(b) (4)	

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered '25 Feb 2021 15:15'	System	26 Feb 2021 02:30:09

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Right Arm (RIGHT ARM)'	Norma Frederick (b) (4)	26 Feb 2021 02:30:09

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'ONCE'	System	26 Feb 2021 02:30:09

**US3792094**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:52:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 02:30:09



**US3792094**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	(b) (4) Norma Frederick (b) (4)	26 Feb 2021 02:30:14

**US3792094**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:58:39
User entered 'I'	System	26 Feb 2021 02:30:14

**US3792094**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	Ann Marie Milliken	05 Mar 2021 17:36:17

**US3792094**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered '5 Mar 2021'	Ann Marie Milliken	05 Mar 2021 17:36:17

**US3792094**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 17:36:17

**US3792094**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:52:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered empty.	Ann Marie Milliken (b) (4)	05 Mar 2021 17:36:17

**US3792094**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:54
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
User entered 'Yes (Y)'	Ann Marie Milliken	05 Mar 2021 17:36:22
	(b) (4)	

**US3792094**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:52:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:31:54
User entered 'I'	System	05 Mar 2021 17:36:22



**US3792094**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	31 Mar 2021 20:12:08
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '31 Mar 2021'	Norma Frederick (b) (4)	31 Mar 2021 20:12:08
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	31 Mar 2021 20:12:08
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:52:10**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 20:12:08

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '31 Mar 2021'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '12:32'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 12:32'	System	31 Mar 2021 20:11:57



**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '97.8' F	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered 'Oral (Oral)'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	31 Mar 2021 20:11:57

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '60'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 20:11:57

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '16'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 20:11:57

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '140'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	



**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 20:11:57

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '74'	Norma Frederick (b) (4)	31 Mar 2021 20:11:57
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:52:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 20:11:57

**US3792094**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	31 Mar 2021 20:11:17
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:52:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	31 Mar 2021 20:11:17
	(b) (4)	

US3792094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 20:10:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 20:10:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4)	31 Mar 2021 20:10:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 20:10:28
User entered empty.	Norma Frederick (b) (4)	31 Mar 2021 20:10:28
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '31 Mar 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	31 Mar 2021 20:10:52
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	31 Mar 2021 20:10:28
	(b) (4)	

**US3792094**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:42
	(b) (4)	
User entered '12:45' reason for change: Data Entry Error	Norma Frederick (b) (4)	31 Mar 2021 20:10:52
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	31 Mar 2021 20:10:28
	(b) (4)	



**US3792094**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:52:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 12:45'	System	31 Mar 2021 20:10:52
User entered empty.	System	31 Mar 2021 20:10:28

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:52:10**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:07
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:29:56
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:32:48

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:34
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:02
User entered	System	26 Oct 2020 22:00:57
'USA-US057-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 22:00:57

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:39
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:36:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:36:35
Data point term sent to Coder	System	05 Nov 2020 00:35:55
Coding entries removed.	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:35:02
User entered 'ACUTE KIDNEY INJURY' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:35:02
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal impairment, LLT: Function kidney decreased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:40:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 22:40:35
Data point term sent to Coder	System	23 Oct 2020 22:39:44
User entered 'DECREASED KIDNEY FUNCTION'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 15:03:19
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'UPDATED ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:16:46
DataPoint Un-verified.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:16:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:16:22
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:06:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:25:37
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:41
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:45
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:47
User entered '20 Oct 2020'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:54
User entered empty.	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:25:57
User entered 'No (N)' reason for change: Per Query Resolution	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:02:04
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:25:59
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)	05 Nov 2020 19:31:20
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 'recovered SAE ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:02:27
	(b) (4)	
User entered '22 Oct 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	05 Nov 2020 00:02:04
	(b) (4)	
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)	02 Nov 2020 15:10:08
User entered empty.	Norma Frederick (b) (4)	23 Oct 2020 22:38:58
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:01
User entered empty.	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:26:03
User closed query 'PV Query: As the event resulted in hospitalization, please confirm he severity of grade 2.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:31:49
Query 'PV Query: As the event resulted in hospitalization, please confirm he severity of grade 2.' answered with 'changed severity ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:02:45
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	Norma Frederick (b) (4)	05 Nov 2020 00:02:04
	(b) (4)	
User opened query 'PV Query: As the event resulted in hospitalization, please confirm he severity of grade 2.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:12:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:04
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:10
User entered '0'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:12
User entered '0'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:14
User entered 'I'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:30
User entered '20 Oct 2020'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:34
User entered '22 Oct 2020'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:37
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:26:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:00
User entered '0'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:10
User entered '0'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:04
User entered '0'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:06
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:08
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

US3792094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Per CDM: Per CCGs p. 35, Action taken with investigational product should be marked as "Not Applicable" only If adverse event started BEFORE first dose, If adverse event started and ended during a time period when study dose was interrupted (not given/held) or If adverse event started AFTER last dose. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:11:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:47
User closed query 'PV Query: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses, please update action taken to None.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:18
Query 'PV Query: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses, please update action taken to None.' answered with 'updated please remove query' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:04:51
Query 'Per CDM: Per CCGs p. 35, Action taken with investigational product should be marked as "Not Applicable" only If adverse event started BEFORE first dose, If adverse event started and ended during a time period when study dose was interrupted (not given/held) or If adverse event started AFTER last dose. Please review and update as appropriate. ' answered with 'changed to NONE' (Site from DM).	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:02:58
User entered 'None (NONE)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	05 Nov 2020 00:02:04
User opened query 'PV Query: PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will be receiving further IP doses, please update action taken to None.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:11:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs p. 35, Action taken with investigational product should be marked as "Not Applicable" only If adverse event started BEFORE first dose, If adverse event started and ended during a time period when study dose was interrupted (not given/held) or If adverse event started AFTER last dose. Please review and update as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:02:59
User entered 'Not Applicable (NOT APPLICABLE)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:19
User entered '0'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:24
User entered 'I'	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:28:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:28:25
User entered '0'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:28:35
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:26
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated to recovered' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:03:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 00:02:04
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)	02 Nov 2020 15:10:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:28:39
User entered empty.	Norma Frederick (b) (4) (b) (4)	23 Oct 2020 22:38:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'PV query: Please provide subject's medical history including preexisting conditions that may impact renal function.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:49:50
User closed query 'PV Query: Please provide any additional treatment given for the event. Please add all treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 11:49:48
Query 'PV Query: Please provide any additional treatment given for the event. Please add all treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'updated CM eCRF' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:47:10
Query 'PV query: Please provide subject's medical history including preexisting conditions that may impact renal function.' answered with 'updated medical history eCRF' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:47:01
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)	05 Nov 2020 19:33:07
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)	05 Nov 2020 19:33:01
User closed query 'PV Query: Please provide any relevant laboratory (i.e. electrolytes, BUN, creatinine, GFR on admission and discharge) and diagnostic test results (i.e. renal ultrasound, CT). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 19:32:41
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 'send med records to safety ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 01:40:10
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 'no covid 19 test done ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 01:39:48
Query 'PV Query: Please provide any relevant laboratory (i.e. electrolytes, BUN, creatinine, GFR on admission and discharge) and diagnostic test results (i.e. renal ultrasound, CT). Please include units and reference ranges if applicable.' answered with 'included in uploaded medical records ' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 01:39:37
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'added to con meds list' (Site from Safety).	Norma Frederick (b) (4)	05 Nov 2020 00:03:35
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)	02 Nov 2020 15:12:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide subject's medical history including preexisting conditions that may impact renal function.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:12:24
User opened query 'PV Query: Please provide any additional treatment given for the event. Please add all treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:11:40
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)	02 Nov 2020 15:10:53
User opened query 'PV Query: Please provide any relevant laboratory (i.e. electrolytes, BUN, creatinine, GFR on admission and discharge) and diagnostic test results (i.e. renal ultrasound, CT). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:10:43
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 15:10:37
User entered 'Sub I note: spoke with patient for day 15 safety follow up phone call. Woke up Tuesday morning 10.20.20 and his entire body was swollen. Went to the hospital and was admitted. Released yesterday , (10/22/2020). His kidney function was down to 44%. Was given lasix, which helped.'	Norma Frederick (b) (4)	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:16:22
User entered '0'	System	23 Oct 2020 22:38:58



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 22:38:58

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Diabetes Mellitus. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 15:03:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 16:10:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 16:10:54
	(b) (4)	
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Diabetes Mellitus. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' answered with 'updated ' (Site from DM).	Norma Frederick (b) (4)	14 Jan 2021 23:36:21
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 23:35:25
Coding entries removed.	Norma Frederick (b) (4)	14 Jan 2021 23:34:34
	(b) (4)	
User entered 'Worsening of Diabetes Mellitus' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Jan 2021 23:34:34
	(b) (4)	
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Diabetes Mellitus. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 22:15:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Carbohydrate tolerance analyses (incl diabetes), PT: Blood glucose increased, LLT: Blood glucose increased - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:07:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:07:49
Data point term sent to Coder	System	13 Nov 2020 19:06:28
User entered 'ELEVATED BLOOD GLUCOSE'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '20 Oct 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User entered empty.	System	13 Nov 2020 19:06:23

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:04:36
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'per subject report diet change and continuous glucose monitoring has brought blood sugar levels to normal' (Site from DM).	Norma Frederick (b) (4)	26 Feb 2021 02:35:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Feb 2021 02:34:53
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:41:41
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 15:04:26
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'data updated ' (Site from System).	Norma Frederick (b) (4)	26 Feb 2021 02:36:09
	(b) (4)	
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Feb 2021 02:35:11
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	26 Feb 2021 02:35:11
User entered '11 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Feb 2021 02:35:11
	(b) (4)	
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	26 Feb 2021 02:34:53
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User entered empty.	System	13 Nov 2020 19:06:23

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Norma Frederick (b) (4)	14 Jan 2021 23:34:34
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:52:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'I'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Norma Frederick (b) (4)	26 Feb 2021 02:36:21
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:06:23
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User entered '0'	System	13 Nov 2020 19:06:23

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26
User entered '1'	System	13 Nov 2020 19:06:23

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:26

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Right Kidney Cyst. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 11:52:17
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Right Kidney Cyst. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' answered with 'REMOVED FROM AE AS CYST IS NOT WORSENING. ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:10:53
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Right Kidney Cyst. If yes, please update to reflect the term worsening as appropriate and ensure that the Severity is greater than Grade 1/Mild. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 22:17:29
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Cyst of kidney - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 19:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 19:09:48
Data point term sent to Coder	System	13 Nov 2020 19:08:32
User entered 'RIGHT KIDNEY CYST'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 19:08:03

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '20 Oct 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:08:03

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:08:03

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	



US3792094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:10

None

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	13 Nov 2020 19:08:26
User entered '1' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	13 Nov 2020 19:08:03
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 19:08:03
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 19:08:03

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:08:03



US3792094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User coded data point as SOC: Renal and urinary disorders, HLT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Renal impairment, LLT: Function kidney decreased - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Jan 2021 00:04:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 00:04:59
Data point term sent to Coder	System	14 Jan 2021 23:48:36
User entered 'DECREASED KIDNEY FUNCTION'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'No (N)'	(b) (4) Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '22 Oct 2020'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered empty.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered '0'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered empty.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered empty.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered '0'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Norma Frederick (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'None (NONE)'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:10

None

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	14 Jan 2021 23:48:28
User entered '1' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Jan 2021 23:48:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	14 Jan 2021 23:48:22
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Norma Frederick (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 21:04:32
User entered empty.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:48:22
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:48:22

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Nail injury, LLT: Nail injury - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 11:46:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 11:46:49
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 23:51:36
User entered 'RIGHT GREAT TOENAIL INJURY'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '12 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User entered empty.	System	14 Jan 2021 23:51:05

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	10 Mar 2021 21:03:39
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '26 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4)	10 Mar 2021 21:03:39
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User entered empty.	System	14 Jan 2021 23:51:05

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'None (NONE)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'I'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Norma Frederick (b) (4)	10 Mar 2021 21:03:39
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:51:05
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User entered '0'	System	14 Jan 2021 23:51:05

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40
User entered '1'	System	14 Jan 2021 23:51:05

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:40

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 02:43:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 02:43:22
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 02:42:46
User entered 'Upper Respiratory Infection'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '29 Jan 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User entered empty.	System	26 Feb 2021 02:42:13

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '6 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User entered empty.	System	26 Feb 2021 02:42:13

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'None (NONE)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'I'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

US3792094

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 21:04:32
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 02:42:13
	(b) (4)	

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User entered '0'	System	26 Feb 2021 02:42:13



**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46
User entered '1'	System	26 Feb 2021 02:42:13

**US3792094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:06:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:52:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:07
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)'	Norma Frederick (b) (4)	04 Nov 2020 23:53:21

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 20:59:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:59:27
Data point term sent to Coder	System	06 Nov 2020 20:58:41
User entered 'pregabalin'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'diabetic neuropathy'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '100'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'three times daily (TID)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:58:25

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2018'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 20:58:25
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Nov 2020 20:58:25

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:58:25

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:58:25

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 21:00:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 21:00:33
Data point term sent to Coder	System	06 Nov 2020 20:59:43
User entered 'jardiance'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'diabetes mellitus, type 2'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '25'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2018'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 22:04:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 22:04:32
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 22:04:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:59:04
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:59:04
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:59:04

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:59:04

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:59:04

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
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.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 21:32:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:32:24
Data point term sent to Coder	System	06 Nov 2020 21:00:45
User entered 'carvedilol'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'hypertension'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '25'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 20:59:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 20:59:57
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 20:59:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:59:57



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:59:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 22:09:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:09:27
Data point term sent to Coder	System	06 Nov 2020 22:08:20
User entered 'Tamsulosin'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'benign prostatic hyperplasia'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0.4'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:07:31

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:07:31
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:07:31

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:07:31

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:07:31

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 23:50:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:50:22
Data point term sent to Coder	System	06 Nov 2020 22:08:18
User entered 'duloxetine'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'diabetic neuropathy'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '60'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 18:39:44
User entered 'UN UNK 2018' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 18:39:44
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	06 Nov 2020 22:08:11
User entered 'un UNK 2918'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:11

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:11
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:11

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:11

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:08:11

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
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.	(b) (4) Coder Import (b) (4)	06 Nov 2020 23:31:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:31:22
Data point term sent to Coder	System	06 Nov 2020 22:09:21
User entered 'aspirin'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'cardiac prophylaxis'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '81'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	13 Nov 2020 18:40:22
User entered 'UN UNK 2018' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 18:40:22
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 22:08:43
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:08:43
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:08:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:08:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:11:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:11:23
Data point term sent to Coder	System	06 Nov 2020 22:10:22
User entered 'losartin'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'renal prophylaxis'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '100'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '20 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User entered '1'	System	06 Nov 2020 22:09:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User entered '1'	System	06 Nov 2020 22:09:33



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:24:02
User entered '804 (804)'	System	06 Nov 2020 22:09:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 22:11:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:11:21
Data point term sent to Coder	System	06 Nov 2020 22:10:23
User entered 'pantoprazole'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'acid reflux'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '40'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:10:08

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2008'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:10:08
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:10:08

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:10:08

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:10:08

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EICOSAPENTAENOIC ACID ETHYL ESTER, PRODUCTSYNONYM: VASCEPA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 22:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:12:23
Data point term sent to Coder	System	06 Nov 2020 22:11:27
User entered 'vascepa'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'hypercholesterolemia'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '2'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'g (g)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:24

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:24
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 22:11:24

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:11:24

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:11:24

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 22:13:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 22:13:25
Data point term sent to Coder	System	06 Nov 2020 22:12:29
User entered 'melatonin'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'insomnia'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '10'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'as needed (PRN)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:11:58

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'un UNK 2010'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:11:58
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:11:58

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:11:58

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 22:11:58

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:17:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:17:23
Data point term sent to Coder	System	06 Nov 2020 22:16:34
User entered 'albuterol inhaler'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'COPD'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '1'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'puff (PUFF)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'three times daily (TID)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'UN UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:16:05

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:16:05
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Nov 2020 22:16:05

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:16:05



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:16:05

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Nov 2020 07:56:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:56:27
Data point term sent to Coder	System	06 Nov 2020 22:17:34
User entered 'BREO ELLIPTA (FLUTCASONE FUROATE VILANTEROL'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'COPD'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g.200/25 mcg, 100/25 mcg, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:59:13
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g.200/25 mcg, 100/25 mcg, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:20:56
User entered '200/25' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:20:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g.200/25 mcg, 100/25 mcg, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 12:38:01
User entered 'I'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:10

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:19:05
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DATA ENTRY ERROR ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	10 Mar 2021 21:05:26
User entered 'ug (ug)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	10 Mar 2021 21:05:18
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 13:45:31
User entered 'mg (mg)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:20:49
User entered 'puff (PUFF)'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'UN UNK 2018'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:17:33
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 22:17:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 22:17:33

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:26:29
Data point term sent to Coder	System	06 Nov 2020 22:19:37
User entered 'LASIX'	Norma Frederick (b) (4) (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'ACUTE KIDNEY INJURY'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '40'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '20 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '22 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User entered '2'	System	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User entered '1'	System	06 Nov 2020 22:18:43

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:28
User entered '804 (804)'	System	06 Nov 2020 22:18:43

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:26:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:26:29
Data point term sent to Coder	System	06 Nov 2020 22:19:37
User entered 'LASIX'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'ACUTE KIDNEY INJURY'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '40'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '22 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '05 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User entered '1'	System	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User entered '1'	System	06 Nov 2020 22:19:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:33
User entered '804 (804)'	System	06 Nov 2020 22:19:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:28:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:28:27
Data point term sent to Coder	System	06 Nov 2020 22:21:39
User entered 'INSULIN GLARGINE'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'DIABETES MELLITUS TYPE 2'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '45'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'IU (IU)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Subcutaneous (SUBCUTANEOUS)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'UN UNK 2015'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '28 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User entered '1'	System	06 Nov 2020 22:20:50

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User entered '1'	System	06 Nov 2020 22:20:50



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:42
User entered '804 (804)'	System	06 Nov 2020 22:20:50

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 22:05:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 22:05:52
Data point term sent to Coder	System	13 Nov 2020 18:43:37
Coding entries removed.	Scarlett Hammett (b) (4)	13 Nov 2020 18:42:51
User entered 'ACETAMINOPHEN 325MG / OXYCODONE 5' reason for change: Data Entry Error	Scarlett Hammett (b) (4)	13 Nov 2020 18:42:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:38:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 22:38:22
Data point term sent to Coder	System	06 Nov 2020 22:22:41
User entered 'ACETAMINOPHEN'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'ACUTE KIDNEY INJURY'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '5/325'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'four times daily (QID)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '20 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '22 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:21:51



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User entered '4'	System	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User entered '1'	System	06 Nov 2020 22:21:51

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:49
User entered '804 (804)'	System	06 Nov 2020 22:21:51

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:52:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:52:28
Data point term sent to Coder	System	06 Nov 2020 22:23:41
User entered 'HUMALOG'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'ELEVATED BLOOD GLUCOSE'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '100'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'IU (IU)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'twice daily (BID)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Subcutaneous (SUBCUTANEOUS)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '20 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '22 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User entered '2'	System	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User entered '1'	System	06 Nov 2020 22:23:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:56
User entered '804 (804)'	System	06 Nov 2020 22:23:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:49:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:49:47
Data point term sent to Coder	System	13 Nov 2020 18:48:52
User entered 'TRAZODONE'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'INSOMNIA'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '50'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Ann Marie Milliken	18 Nov 2020 19:13:21
User entered 'Other (OTHER)'	(b) (4) Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	18 Nov 2020 19:13:21
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	13 Nov 2020 18:47:53
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: This Con Med was added on 21 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 11:58:18
Query 'Per DM CLR: This Con Med was added on 21 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'This medication was given in hospital. subject states it is due to not being able to sleep in hospital as they kept waking him up to run tests and take vitals. no worsening. ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:24:37
User opened query 'Per DM CLR: This Con Med was added on 21 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 12:39:40
Un-reviewed for Data Management.	(b) (4), (b) (6)	05 Jan 2021 12:39:21
Reviewed for Data Management.	(b) (4), (b) (6)	05 Jan 2021 12:39:17
User entered '21 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:47:53



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '21 Oct 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User entered '1'	System	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User entered '1'	System	13 Nov 2020 18:47:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:53
User entered '804 (804)'	System	13 Nov 2020 18:47:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:20:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:20:41
Data point term sent to Coder	System	13 Nov 2020 18:50:54
User entered 'NITROGLYCERIN'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 10:20:39
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'it is not known why the medication was given as it is not indicated in medical records. ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:29:04
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 12:40:13
User entered 'ACUTE KIDNEY INJURY'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 10:20:41
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct as entered and seen in medical records ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:29:26
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 12:40:32
User entered '04'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Other (OTHER)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'SUBLINGUEL'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '20 Oct 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '20 Oct 2020'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User entered '1'	System	13 Nov 2020 18:50:18

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User entered '1'	System	13 Nov 2020 18:50:18



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:45
User entered '804 (804)'	System	13 Nov 2020 18:50:18

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4)	14 Jan 2021 23:43:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	14 Jan 2021 23:43:59
Data point term sent to Coders	System	14 Jan 2021 23:34:25
Coding entries removed.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:33:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	13 Nov 2020 18:53:48
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	13 Nov 2020 18:53:48
Data point term sent to Coders	System	13 Nov 2020 18:52:57
User entered 'INSULIN GLARGINE'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Elevated blood glucose' reason for change: Data Entry Error	Norma Frederick (b) (4)	14 Jan 2021 23:33:27
	(b) (4)	
User entered 'DIABETES MELLITUS TYPE 2'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '50'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'IU (IU)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'once daily (QD)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. '(Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 11:58:47
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:33:20
' answered with 'updated to worsening of blood glucose which is an ongoing AE' (Site from DM). User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. '(Site from DM).	(b) (4), (b) (6)	05 Jan 2021 12:41:08
User entered '29 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:52:01

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:52:01
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:52:01

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 18:52:01

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 18:52:01

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Nov 2020 05:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:19:41
Data point term sent to Coder	System	13 Nov 2020 18:57:04
User entered 'NOVALOG'	Scarlett Hammett (b) (4) (b) (4)	13 Nov 2020 18:56:22

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'DIABETES MELLITUS TYPE 2'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '100'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'IU (IU)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'other (OTHER)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:52:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '6 TIMES PER DAY'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'UN UNK 2008'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Scarlett Hammett (b) (4)	13 Nov 2020 18:56:22
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:56:22

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:56:22

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:56:22

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:52:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 10:35:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 10:35:50
Data point term sent to Coder	System	14 Jan 2021 23:56:42
User entered 'TRAMADOL'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'RIGHT GREAT TOENAIL INJURY'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:52:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appears to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:12:49
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appears to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 22:45:09
User entered '50' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:44:52
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appears to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:13:59
User entered '500'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'other (OTHER)'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'EVERY 4 HOURS'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '12 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '13 Jan 2021'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User entered empty.	System	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User entered empty.	System	14 Jan 2021 23:56:12

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:30
User entered empty.	System	14 Jan 2021 23:56:12

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 08:00:15
Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'date entered was in error. confirmed by subject ' (Site from DM).	Norma Frederick (b) (4) (b) (4)	26 Feb 2021 02:57:50
User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:28:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:58:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:58:59
Data point term sent to Coder	System	14 Jan 2021 23:57:44
User entered 'FLU VACCINE'	Norma Frederick (b) (4) (b) (4)	14 Jan 2021 23:57:17



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Yes (Y)'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'INFLUENZA PROPHYLAXIS'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'I'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Other (OTHER)'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'INJECTION'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once (ONCE)'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Norma Frederick (b) (4)	14 Jan 2021 23:57:17



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 02:57:31
User entered '15 Oct 2020'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '15 Dec 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	26 Feb 2021 02:57:31
User entered '15 Oct 2020'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User entered empty.	System	14 Jan 2021 23:57:17

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User entered empty.	System	14 Jan 2021 23:57:17



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:37
User entered empty.	System	14 Jan 2021 23:57:17

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 05:12:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 05:12:06
Data point term sent to Coder	System	26 Feb 2021 05:11:33
User entered 'Prednisone'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Upper Respiratory Infection'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '40'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '30 Jan 2021'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '04 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:10:53



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User entered '1'	System	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User entered '1'	System	26 Feb 2021 05:10:53

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:11
User entered '804 (804)'	System	26 Feb 2021 05:10:53

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:52:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 05:13:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 05:13:20
Data point term sent to Coder	System	26 Feb 2021 05:12:34
User entered 'azithromycin'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'upper respiratory infection'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '250'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '30 Jan 2021'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '05 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User entered '1'	System	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User entered '1'	System	26 Feb 2021 05:11:57

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:23
User entered '804 (804)'	System	26 Feb 2021 05:11:57

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PROMETHAZINE HYDROCHLORIDE, PRODUCTSYNONYM: PROMETHAZINE DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:42:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:42:50
Data point term sent to Coder	System	26 Feb 2021 05:14:34
User entered 'Promethazine DM (promethazine 6.25/dextromethorphan15mg)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'upper respiratory infection'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '10'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mL (mL)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '30 Jan 2021'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '05 Feb 2021'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Norma Frederick (b) (4)	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User entered '1'	System	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User entered '1'	System	26 Feb 2021 05:13:40

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:40
User entered '804 (804)'	System	26 Feb 2021 05:13:40

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:52:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 10:05:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 10:05:54
Data point term sent to Coder	System	05 Mar 2021 21:12:06
User entered 'Ibuprofen'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Bilateral Carpal Tunnel Syndrome, Left Ann Marie Milliken Shoulder Osteoarthritis'	(b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '800'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'mg (mg)'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'once daily (QD)'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Oral (ORAL)'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:52:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered empty.	Ann Marie Milliken	05 Mar 2021 21:11:30
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:52:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	05 Mar 2021 21:11:41
User entered 'UN UNK 2017' reason for change: Data Entry Error	System	05 Mar 2021 21:11:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Ann Marie Milliken	05 Mar 2021 21:11:41
User entered 'UNK 2017' (non-conformant).	(b) (4)	05 Mar 2021 21:11:30
	System	05 Mar 2021 21:11:30
	Ann Marie Milliken	05 Mar 2021 21:11:30
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '0'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered '1 Mar 2021'	Ann Marie Milliken	05 Mar 2021 21:11:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:52:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'No (N)'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User entered '1'	System	05 Mar 2021 21:11:30

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User entered '1'	System	05 Mar 2021 21:11:30



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:17:02
User entered '804 (804)'	System	05 Mar 2021 21:11:30

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:52:10

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Mar 2021 21:14:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 21:14:58
Data point term sent to Coder	System	05 Mar 2021 21:14:07
User entered 'Acetaminophen'	Ann Marie Milliken (b) (4)	05 Mar 2021 21:13:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
User entered 'Bilateral Carpal Tunnel Syndrome, Left Shoulder Osteoarthritis'	(b) (4) Ann Marie Milliken (b) (4)	05 Mar 2021 21:13:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '650'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'mg (mg)'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:52:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:52:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'twice daily (BID)'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	



US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:52:10

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Oral (ORAL)'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

US3792094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:52:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '4 Mar 2021'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered '0'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'Yes (Y)'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered empty.	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:14:07
	(b) (4)	
User entered 'No (N)'	Ann Marie Milliken	05 Mar 2021 21:13:33
	(b) (4)	



**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 21:13:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 21:13:33

**US3792094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:52:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 21:13:33

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:52:10**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:07
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Norma Frederick (b) (4)	06 Nov 2020 20:47:27
User entered 'No (N)'	(b) (4)	
	Norma Frederick (b) (4)	04 Nov 2020 23:58:06
	(b) (4)	

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:52:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '22 Oct 2020' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 20:56:50
	(b) (4)	
User entered '6 Nov 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:55:40
	(b) (4)	

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered 'renal ultrasound'	Norma Frederick (b) (4)	06 Nov 2020 20:55:40
	(b) (4)	

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Norma Frederick (b) (4)	06 Nov 2020 20:56:50
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Norma Frederick (b) (4)	06 Nov 2020 20:55:40
	(b) (4)	

US3792094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:52:10

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:55:40
	(b) (4)	



**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:52:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '22 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:56:01

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'echocardiogram'	Norma Frederick (b) (4)	06 Nov 2020 20:56:01

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Adverse Event (AE)'	Norma Frederick (b) (4)	06 Nov 2020 20:56:01

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:52:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:27
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:56:01

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:52:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:33
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '22 Oct 2020'	Norma Frederick (b) (4)	06 Nov 2020 20:56:20

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:33
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'chest x-ray'	Norma Frederick (b) (4)	06 Nov 2020 20:56:20

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:33
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered 'Adverse Event (AE)'	Norma Frederick (b) (4)	06 Nov 2020 20:56:20

**US3792094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:52:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:56:33
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered empty.	Norma Frederick (b) (4)	06 Nov 2020 20:56:20



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 21:38:27

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '4'	System	15 Jan 2021 15:13:57
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 21:38:27

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '4'	System	15 Jan 2021 15:13:57
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
User entered '26/Oct/2020 22:02'	(b) (4) System	26 Oct 2020 22:02:16

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:52:10

**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.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 21:38:27

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '4'	System	15 Jan 2021 15:13:57
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
User entered '05/Nov/2020 19:33'	(b) (4) System	05 Nov 2020 19:33:45

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:52:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 19:33:45

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 21:38:27

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '4'	System	15 Jan 2021 15:13:57
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '09/Nov/2020 06:50'	(b) (4) System	09 Nov 2020 11:50:17

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:52:10

**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.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 15:13:47
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 11:50:17

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:03
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'USA-US057-2020-MRNA-1273-P301000001'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:35:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57



**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:58
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:57
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Yes (Y)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:51
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'No (N)'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:48
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Abram'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:46
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Burgher'	System	26 Oct 2020 22:00:57



US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:44
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '3900 East Camelback Road'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '2525 W. Greenway Road' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '3900 East Camelback Road'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered 'Phoenix'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:40
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered empty.	Norma Frederick (b) (4) (b) (4)	04 Nov 2020 21:38:27

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:10

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 11:50:09
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:34:38
Un-reviewed for Safety.	System	05 Nov 2020 19:33:45
User entered '85018'	System	05 Nov 2020 19:33:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
Un-reviewed for Safety.	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
User entered '85023' reason for change: Data Entry Error	Norma Frederick (b) (4)	04 Nov 2020 21:38:27
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 22:01:42
User entered '85018'	System	26 Oct 2020 22:00:57

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:34:37
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:33:29
User entered 'US'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:52:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
	(b) (4)	
User entered '4'	System	15 Jan 2021 15:13:57
Signature has been broken.	System	09 Nov 2020 11:50:17
User entered '3'	System	09 Nov 2020 11:50:17
User signature succeeded.	Abram Burgher (b) (4)	05 Nov 2020 23:31:22
	(b) (4)	
User entered '2'	System	05 Nov 2020 19:33:45
User entered '1'	System	26 Oct 2020 22:02:16

**US3792094**

**Folder: SAE USA-US057-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:52:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
User entered '15/Jan/2021 10:13'	(b) (4) System	15 Jan 2021 15:13:57

US3792094

Folder: SAE USA-US057-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:52:10

**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.	Abram Burgher (b) (4)	19 Feb 2021 21:59:51
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 15:14:00
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 15:13:57