

US3912114 (Prod: Synexus - Optimal Research - Austin)

Generated By: KC Joubran

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US3912114

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

US3912114

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

US3912114

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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 16:21:53

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Date of Informed Consent (dd MMM yyyy) 04 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	☐
Amendment 2	☐
Amendment 3	☒
Amendment 4	☐
Amendment 5	☐

Was participant enrolled in the study?

Yes	☒
No	☐

If No, indicate reason for screen fail

Withdrew Consent	☐
Inclusion/Exclusion	☐
Cohort Full	☐
Other	☐

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	☐
No	☒

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:21:53

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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 16:21:53

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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 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	PENICILLIN ALLERGY (RASH)
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	LIPITOR ALLERGY (RASH)
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	GADOLINIUM DERIVATIVES (RASH)
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	FELDENE ALLERGY (RASH)
Start date (dd MMM yyyy)	UN UNK 1978
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1978
Start Year (derived)	1978
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 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	AUG 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	BILATERAL CATARACT SURGERY
Start date (dd MMM yyyy)	UN AUG 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2018
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2018
Start Year (derived)	2018
Stop Month and Year (derived)	AUG 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	TRIPLE NEGATIVE BREAST CANCER LEFT BREAST
Start date (dd MMM yyyy)	UN APR 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2011
Stop date completely unknown	False
Start Month and Year (derived)	APR 2011
Start Year (derived)	2011
Stop Month and Year (derived)	NOV 2011
Stop Year (derived)	2011

US3912114

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	LUMPECTOMY LEFT BREAST
Start date (dd MMM yyyy)	02 MAY 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	02 MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2011
Start Year (derived)	2011
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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 (13)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	BODY ACHES
Start date (dd MMM yyyy)	31 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Condition	SEASONAL ALLERGIES (COUGH, RUNNY NOSE)
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:20 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:20
Height (<i>xxx.x</i>)	60.0 in
Weight (<i>xxx.x</i>)	163.0 lb
BMI (<i>xxx.x</i>)	31.90032 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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 16:21:53

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 16:21:53

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Date of assessment (dd MMM yyyy) 04 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2001

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:53

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

OVER 65 YEARS OLD

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 16:21:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

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

What was the participant's randomization number? 190045

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

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 16:21:53

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:20
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 17:12
Temperature (xxx.x)	36.1 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 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 16:21:53

Generated On: 10 Jun 2021 10:16:35

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 16:21:53

Generated On: 10 Jun 2021 10:16:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 04 SEP 2020

What was the treatment time? (00:00-23:59) 16:25 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 16:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

15:48 (24 HR)

Collection date and time (derived)

04 SEP 2020 15:48

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:51	04 SEP 2020 15:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:53

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 04 SEP 2020 17:27

PC Open Date & Time 04 SEP 2020 16:45

PC Close Date & Time 04 SEP 2020 19:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

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

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

PC Time Stamp 04 SEP 2020 20:55

PC Open Date & Time 04 SEP 2020 20:10

PC Close Date & Time 05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.8 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	05 SEP 2020 19:59
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

97.8 °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

06 SEP 2020 16:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 15:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

08 SEP 2020 16:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:33

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

97.0 °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

10 SEP 2020 20:05

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 17:28

PC Open Date & Time

04 SEP 2020 16:45

PC Close Date & Time

04 SEP 2020 19:15

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:56

PC Open Date & Time

04 SEP 2020 20:10

PC Close Date & Time

05 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 16:14

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 15:22

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 16:36

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:34

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 20:05

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 17:28
PC Open Date & Time	04 SEP 2020 16:45
PC Close Date & Time	04 SEP 2020 19:15

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:57
PC Open Date & Time	04 SEP 2020 20:10
PC Close Date & Time	05 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes ☐	
PC Time stamp	05 SEP 2020 20:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes ☐	
PC Time stamp	06 SEP 2020 16:15
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

Yes ☐	
PC Time stamp	07 SEP 2020 15:23
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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)

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes ☐	
PC Time stamp	08 SEP 2020 16:36
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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)

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes ☐	
PC Time stamp	09 SEP 2020 19:34
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

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EAB) (1725)

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes ☐	
PC Time stamp	10 SEP 2020 20:06
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3912114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

REASON FOR MISSED SAFETY
CALL IS UNKNOWN.

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:20
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3912114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

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

SUBJECT DID NOT MEET I/E AT SCREENING SO THE DECISION WAS MADE NOT TO DOSE HER AGAIN.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3912114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

02 OCT 2020 12:00

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	02 OCT 2020 12:05
Nasopharyngeal Swab 2	No		

US3912114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	04 NOV 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	04 NOV 2020 12:23
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3912114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	4 NOV 2020
Collection time (00:00-23:59)	13:04 (24 HR)
Collection date and time (derived)	4 NOV 2020 13:04

US3912114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:54

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:29:04

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 18:00:02

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 08:14:06
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

26 NOV 2020 17:43:25

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	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 ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 08:27:54
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☒

Yes ☐

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

06 DEC 2020 06:55:25

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

13 DEC 2020 10:20:15

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 17:23:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 19:55:38

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 06:11:43

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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	10 JAN 2021 06:07:17
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 07:10:49

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

26 JAN 2021 20:50:12

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

02 FEB 2021 12:45:23

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 07:19:57
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

17 FEB 2021 18:24:11

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

21 FEB 2021 07:02:31

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

28 FEB 2021 13:22:48

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

09 MAR 2021 12:03:11

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 16:29:53

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

23 MAR 2021 12:00:22

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

28 MAR 2021 06:13:44

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 08:41:21

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 07:21:32

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 13:07:37

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 16:35:14

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:07:02

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 264

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 320

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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05 AUG 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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12 AUG 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

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19 AUG 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

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26 AUG 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

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02 SEP 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 411

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 446

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 460

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 488

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

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

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US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3912114

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

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Folder: New Safety Follow Up Diary (1)

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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 ☐

US3912114

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

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US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

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US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

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US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 614

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 691

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

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

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

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

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

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

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

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01 SEP 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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08 SEP 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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15 SEP 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3912114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:16:35

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		28 FEB 2021 13:22:27

US3912114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:56:10

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:56:10

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 17:51:53

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	30 MAR 2021

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

Folder OID	VISIT4

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:51:53

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3912114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:51:53

Generated On: 10 Jun 2021 10:16:35

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.

US3912114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 17:51:53

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	13:37 (24 HR)
Collection date and time (derived)	30 MAR 2021 13:37

US3912114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 17:51:53

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912114

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Date of Contact	30 OCT 2020
Time of Contact	11:27
Date and Time of Contact (derived)	30 OCT 2020 11:27
Type of Contact	Clinic Visit - Scheduled ☒ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒ No ☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	16 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	17 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	18 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	19 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	20 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	21 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	22 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	23 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	24 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	25 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	26 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	27 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 OCT 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☒
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	29 OCT 2020

Assessment Not Done	True

O2 Saturation	

O2 Saturation Units	

Temperature	

Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☒
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.5 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☒
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	31 OCT 2020

Assessment Not Done	False

O2 Saturation	99 %

O2 Saturation Units	%

Temperature	36.4 C

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☒
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	01 NOV 2020

Assessment Not Done	False

O2 Saturation	97 %

O2 Saturation Units	%

Temperature	36.4 C

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☒
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	36.4 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Date of Visit 30 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 30 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	1 NOV 2020
Day 5	Yes	3 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3912114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 11:38
Height (xxx.x)	60.0 in
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	184 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912114

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3912114

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 16:21:22

Generated On: 10 Jun 2021 10:16:35

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 OCT 2020

US3912114

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	11 FEB 2021

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

Folder OID	UNBLND_DECIDE

US3912114

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 19:11:32

Generated On: 10 Jun 2021 10:16:35

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ☒ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☒
Date of unblinding (<i>dd MMM yyyy</i>)	11 FEB 2021
Participant randomization assignment	mRNA-1273 ☒ Placebo ☐
Actual Dose 1	mRNA-1273 ☒ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☒
Will participant receive mRNA-1273?	Yes ☒ No ☐
Placebo Only Flag	
Continuing with mRNA-1273	1

US3912114

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3912114

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 14:22
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3912114

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:45
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3912114

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3912114

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

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) 11 FEB 2021

What was the treatment time? (00:00-23:59) 15:08 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 15:08

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: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:21:23

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 FEB 2021

Collection time (00:00-23:59)

14:02 (24 HR)

Collection date and time (derived)

11 FEB 2021 14:02

US3912114

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00 - 23:59)	14:06
Collection Date and Time (derived)	11 FEB 2021 14:06

US3912114

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:56:10

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:56:10

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?	Yes ☒	
	No ☐	
Continuing Flag		1
OLD29 Placebo Flag		1

US3912114

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 21:29:16

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	OLD29

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 21:29:16

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 11:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912114

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 21:29:16

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3912114

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 21:29:16

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	11:53 (24 HR)
Collection date and time (derived)	12 MAR 2021 11:53

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

WORSENING OF
HYPERTENSION

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)

04 SEP 2020

Start time (00:00-23:59)

17:06 (24 HR)

AE start date and time (derived)

04 SEP 2020 17:06

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

INJECTION SITE REACTION
LEFT DELTOID (ITCHING)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

HYPERTENSION, WORSENING

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)

30 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)

04 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

MUCUS IN POSTERIOR
OROPHARYNX

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)

30 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)

4 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID	
Adverse event	RIGHT SHOULDER PAIN
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)	30 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)	1 JAN 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 (5)

Data signed: (b) (4) 06 Apr 2021 21:23:58

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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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID	USA-US211-2020-MRNA-1273-P30 1000005
Adverse event	BROKEN RIGHT HUMERUS
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)	30 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)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	11 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 06 Apr 2021 21:23:58

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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 ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD SURGERY TO REPAIR FRACTURE. SUBJECT WAS HOSPITALIZED OVERNIGHT FOLLOWING SURGERY. SHE IS NOW AT HOME AND DOING WELL.
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (6)

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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 (7)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

STYE (BILATERAL EYES)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 MAR 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 (7)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
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) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

AEID	
Adverse event	SEASONAL ALLERGY- ACTIVE
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)	16 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)	31 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 06 Apr 2021 21:23:58

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication LEVOTHROXIN

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 0.05

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) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication	CRESTOR
Prophylaxis	Yes ☐ No ☒
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

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

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC

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 (5)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication OSTEO BI-FLEX

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

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 (6)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication CALCIUM WITH D3

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 600

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) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 2000

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) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication BIOTIN

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 10,000

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) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication MINOXIDIL 5%

Prophylaxis Yes ☒
No ☐

Indication HAIR LOSS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 31 AUG 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication EXCEDRIN MIGRAINE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 (13)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 05 SEP 2020		
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication BENADRYL 25MG

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE REACTION
LEFT DELTOID

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication BENADRYL, 1%

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE REACTION
LEFT DELTOID

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	9 OCT 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT SHOULDER PAIN

Dose per administration 600

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 8 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 (18)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		1 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT SHOULDER PAIN

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

EVERY 6 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 (19)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 1 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication BROKEN RIGHT HUMERUS
(RELATED TO FALL)

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 2964

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication STYE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

Name of Medication TOBRADEX (TOBRAMYCIN
DEXAMETHASONE 0.3% / 0.1%)

Prophylaxis Yes ☐
No ☒

Indication STYE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 18 Mar 2021 18:26:27

Generated On: 10 Jun 2021 10:16:35

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 16:21:21

Generated On: 10 Jun 2021 10:16:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 NOV 2020	OPEN REDUCTION INTERNAL FIXATION RIGHT HUMERUS	Adverse Event	

US3912114

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Feb 2021 16:21:22

Generated On: 10 Jun 2021 10:16:35

Date of dosing discontinuation (dd MMM yyyy) 2 OCT 2020

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 SUBJECT WAS FOUND TO HAVE NOT MET INCLUSION #7

US3912114

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/NOV/2020 08:11
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

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	01/DEC/2020 18:26
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

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/DEC/2020 07:02
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

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/JAN/2021 19:57
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

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/FEB/2021 09:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 09 Mar 2021 19:56:09

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US211-2020-MRNA-1273-P301000005
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/FEB/2021 09:14
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

US3912114 (Prod: Synexus - Optimal Research - Austin)

US3912114

Form: Participant Creation

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'US3912114'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:19:35

US3912114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Tina Rountree (b) (4)	04 Sep 2020 21:52:52

US3912114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:19:35

US3912114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	04 Sep 2020 21:52:52

US3912114

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'SCRN'	System	04 Sep 2020 21:52:52

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered (b) (6) 1946'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:19:36

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '74'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'YEARS'	System	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '74'	System	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Female (F)'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '1'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Tina Rountree (b) (4)	04 Sep 2020 21:53:22

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 04-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:24:06
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 04-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 17:13:51
User entered '04 Sep 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 17:13:44
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 04-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:05:44
User entered '4 Sep 2020'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Sep 2020'	System	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2020'	System	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Amendment 3 (3)'	Tina Rountree (b) (4)	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Enrollment is recorded as Yes; however, met all criteria is recorded as NO. Please review and reconcile.' (Site from System).	(b) (4)	06 Nov 2020 00:25:26
User opened query 'Enrollment is recorded as Yes; however, met all criteria is recorded as NO. Please review and reconcile.' (Site from System).	System	08 Oct 2020 15:20:41
User closed query 'Enrollment is recorded as Yes; however, met all criteria is recorded as NO. Please review and reconcile.' (Site from System).	System	08 Oct 2020 15:20:37
User opened query 'Enrollment is recorded as Yes; however, met all criteria is recorded as NO. Please review and reconcile.' (Site from System).	System	30 Sep 2020 00:52:53
User entered 'Yes (Y)'	Tina Rountree (b) (4)	04 Sep 2020 21:53:36
	(b) (4)	

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Tina Rountree (b) (4)	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Tina Rountree (b) (4)	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Tina Rountree (b) (4)	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:19:35

US3912114

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '1'	System	06 Nov 2020 00:25:26
User entered empty.	System	08 Oct 2020 15:20:41
User entered '1'	System	08 Oct 2020 15:20:37
User entered empty.	System	30 Sep 2020 00:52:53
User entered '1'	System	04 Sep 2020 21:53:36

US3912114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4) mhutchens1)	19 Feb 2021 16:21:54
User closed query 'Please confirm or clarify the following statement: "US3912114 was diagnosed with hypertension UNAug2020 and started Lisinopril 10mg on 17Aug2020. Subject did not meet Inclusion Criteria #7 per Protocol Amendment 3, but was vaccinated at V1D1. Protocol deviation has been documented and, per discussion with Medical Monitors, subject should continue in study for safety. Upon amending the response to 'Did the participant meet all eligibility criteria?' to 'No' the safety assessment Screening and V1D1 eCRFs became unavailable. At this time, these eCRFs cannot be manually added to the Screening and V1D1 folders when the response is 'No'. Per PPD Lead Clinical Team Manager, the response to this question should be amended to 'Yes' for the necessary Screening and Visit 1 Day 1 eCRFs to populate. Data Management will continue to work on finding a solution for this matter that will allow the site to accurately reflect that the subject did not meet eligibility criteria but was vaccinated at V1D1, and then the response will be amended to 'No' per source documentation.'" (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:46:19

US3912114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Query 'Please confirm or clarify the following statement: "US3912114 was diagnosed with hypertension UNAug2020 and started Lisinopril 10mg on 17Aug2020. Subject did not meet Inclusion Criteria #7 per Protocol Amendment 3, but was vaccinated at V1D1. Protocol deviation has been documented and, per discussion with Medical Monitors, subject should continue in study for safety. Upon amending the response to 'Did the participant meet all eligibility criteria?' to 'No' the safety assessment Screening and V1D1 eCRFs became unavailable. At this time, these eCRFs cannot be manually added to the Screening and V1D1 folders when the response is 'No'. Per PPD Lead Clinical Team Manager, the response to this question should be amended to 'Yes' for the necessary Screening and Visit 1 Day 1 eCRFs to populate. Data Management will continue to work on finding a solution for this matter that will allow the site to accurately reflect that the subject did not meet eligibility criteria but was vaccinated at V1D1, and then the response will be amended to 'No' per source documentation.'" answered with 'corrected and V1D1 entered' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:12:17

US3912114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User opened query 'Please confirm or clarify the following statement: "US3912114 was diagnosed with hypertension UNAug2020 and started Lisinopril 10mg on 17Aug2020. Subject did not meet Inclusion Criteria #7 per Protocol Amendment 3, but was vaccinated at V1D1. Protocol deviation has been documented and, per discussion with Medical Monitors, subject should continue in study for safety. Upon amending the response to 'Did the participant meet all eligibility criteria?' to 'No' the safety assessment Screening and V1D1 eCRFs became unavailable. At this time, these eCRFs cannot be manually added to the Screening and V1D1 folders when the response is 'No'. Per PPD Lead Clinical Team Manager, the response to this question should be amended to 'Yes' for the necessary Screening and Visit 1 Day 1 eCRFs to populate. Data Management will continue to work on finding a solution for this matter that will allow the site to accurately reflect that the subject did not meet eligibility criteria but was vaccinated at V1D1, and then the response will be amended to 'No' per source documentation.'" (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:07:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	06 Nov 2020 00:25:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 15:20:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 15:20:37
User closed query 'PER CDM: Re-Query: Did the participant meet all eligibility criteria? = NO. However, in the enrolment page it was reported as YES for Was participant enrolled in the study? Please review and reconcile or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 06:35:44

US3912114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Query 'PER CDM: Re-Query: Did the participant meet all eligibility criteria? = NO. However, in the enrolment page it was reported as YES for Was participant enrolled in the study? Please review and reconcile or clarify. Thank you.' answered with 'After subject was randomized and vaccinated, it was discovered that subject did NOT meet all eligibility criteria. Subject had recent diagnosis of hypertension and recent initiation of medication to treat hypertension.' (Site from DM).	Timothy Vachris (b) (4)	06 Oct 2020 00:08:43
User closed query 'Subject was diagnosed with hypertension UNAug2020 and started taking Lisinopril 10mg on 17Aug2020. Subject did not meet inclusion criteria #7. If confirmed change answer here to "No" and reason is Inclusion #7' (Site from CRA).	(b) (4), (b) (6)	02 Oct 2020 17:55:56
User opened query 'PER CDM: Re-Query: Did the participant meet all eligibility criteria? = NO. However, in the enrolment page it was reported as YES for Was participant enrolled in the study? Please review and reconcile or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 04:47:58
User closed query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:44:18
User closed query 'Did the subject meet all eligibility criteria? is marked "No", but Subject enrolled is YES. Please review and provide any needed correction.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:44:13
Query 'Did the subject meet all eligibility criteria? is marked "No", but Subject enrolled is YES. Please review and provide any needed correction.' answered with 'Correct as is' (Site from System).	Tina Rountree (b) (4)	30 Sep 2020 00:54:34
Query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' answered with 'Correct as is' (Site from System).	Tina Rountree (b) (4)	30 Sep 2020 00:54:28

US3912114

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Query 'Subject was diagnosed with hypertension UNAUG2020 and started taking Lisinopril 10mg on 17AUG2020. Subject did not meet inclusion criteria #7. If confirmed change answer here to "No" and reason is Inclusion #7' answered with 'Correct as is' (Site from CRA).	Tina Rountree (b) (4)	30 Sep 2020 00:54:23
User opened query 'Did the subject meet all eligibility criteria? is marked "No", but Subject enrolled is YES. Please review and provide any needed correction.' (Site from System).	System	30 Sep 2020 00:52:53
User opened query 'Did the subject meet all eligibility criteria? is marked "No", but Subject was randomized Please review and provide any needed correction.' (Site from System).	System	30 Sep 2020 00:52:53
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	30 Sep 2020 00:52:53
User opened query 'Subject was diagnosed with hypertension UNAUG2020 and started taking Lisinopril 10mg on 17AUG2020. Subject did not meet inclusion criteria #7. If confirmed change answer here to "No" and reason is Inclusion #7' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 23:03:43
User entered 'Yes (Y)'	Tina Rountree (b) (4)	04 Sep 2020 21:52:46

US3912114

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:16:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
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	06 Nov 2020 14:10:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4)	06 Nov 2020 14:10:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Nov 2020 01:10:45
	Tina Rountree (b) (4)	06 Nov 2020 01:10:45
	(b) (4)	

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:13:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:13:34
Data point term sent to Coder	System	06 Nov 2020 14:13:09
User entered 'Penicillin Allergy (rash)'	Mia Rountree (b) (4)	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 1960'	Mia Rountree (b) (4)	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 1960'	System	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '1960'	System	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:12:27

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 09:40:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 09:40:47
Data point term sent to Coder	System	06 Nov 2020 14:13:09
User entered 'Lipitor allergy (rash)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 1990'	Mia Rountree (b) (4)	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 1990'	System	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '1990'	System	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:12:59

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 05:29:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 05:29:40
Data point term sent to Coder	System	06 Nov 2020 14:14:10
User entered 'Gadolinium derivatives (rash)'	Mia Rountree (b) (4)	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 2003'	Mia Rountree (b) (4)	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 2003'	System	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2003'	System	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:13:46

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 23:55:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 23:55:23
Data point term sent to Coder	System	06 Nov 2020 14:15:10
User entered 'Feldene Allergy (rash)'	Mia Rountree (b) (4)	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 1978'	Mia Rountree (b) (4)	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 1978'	System	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '1978'	System	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:15:01

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
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 14:16:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:16:48
Data point term sent to Coder	System	06 Nov 2020 14:16:11
User entered 'Hypertension'	Mia Rountree (b) (4)	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un Aug 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Aug 2020'	System	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2020'	System	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:15:38

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
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 14:16:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:16:47
Data point term sent to Coder	System	06 Nov 2020 14:16:13
User entered 'Hypercholesterolemia'	Mia Rountree (b) (4)	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 2000'	Mia Rountree (b) (4)	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 2000'	System	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2000'	System	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:16:08

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:18:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:18:37
Data point term sent to Coder	System	06 Nov 2020 14:17:13
User entered 'Hypothyroidism'	Mia Rountree (b) (4)	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 2005'	Mia Rountree (b) (4)	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 2005'	System	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2005'	System	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:16:32

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	06 Nov 2020 14:18:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:18:36
Data point term sent to Coder	System	06 Nov 2020 14:17:15
User entered 'Bilateral Cataracts'	Mia Rountree (b) (4)	06 Nov 2020 14:17:10
	(b) (4)	

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 2011'	Mia Rountree (b) (4)	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un Aug 2018'	Mia Rountree (b) (4)	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 2011'	System	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2011'	System	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Aug 2018'	System	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2018'	System	06 Nov 2020 14:17:10

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:18:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:18:38
Data point term sent to Coder	System	06 Nov 2020 14:18:15
User entered 'Bilateral cataract surgery'	Mia Rountree (b) (4)	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un Aug 2018'	Mia Rountree (b) (4)	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un Aug 2018'	Mia Rountree (b) (4)	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Aug 2018'	System	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2018'	System	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Aug 2018'	System	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2018'	System	06 Nov 2020 14:17:47

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Triple negative breast cancer, LLT: Triple negative breast cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Nov 2020 15:01:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 15:01:26
Data point term sent to Coder	System	06 Nov 2020 14:21:19
User entered 'Triple negative breast cancer left breast'	Mia Rountree (b) (4)	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un Apr 2011'	Mia Rountree (b) (4)	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un Nov 2011'	Mia Rountree (b) (4)	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Apr 2011'	System	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2011'	System	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Nov 2011'	System	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2011'	System	06 Nov 2020 14:20:32

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Breast conserving surgery, LLT: Lumpectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:22:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:22:35
Data point term sent to Coder	System	06 Nov 2020 14:21:19
User entered 'Lumpectomy left breast'	Mia Rountree (b) (4)	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 May 2011'	Mia Rountree (b) (4)	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 May 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'May 2011'	System	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2011'	System	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'May 2020'	System	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2020'	System	06 Nov 2020 14:21:18

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:23:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:23:37
Data point term sent to Coder	System	06 Nov 2020 14:22:20
User entered 'Post menopausal'	Mia Rountree (b) (4)	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'UN UNK 2001' reason for change:	Mia Rountree (b) (4)	21 Dec 2020 14:41:12
Data Entry Error	(b) (4)	
User entered 'un UNK 2011'	Mia Rountree (b) (4)	06 Nov 2020 14:21:37
	(b) (4)	

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 2001'	System	21 Dec 2020 14:41:12
User entered 'Jan 2011'	System	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2001'	System	21 Dec 2020 14:41:12
User entered '2011'	System	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:21:37

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:23:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:23:37
Data point term sent to Coder	System	06 Nov 2020 14:22:20
User entered 'Body aches'	Mia Rountree (b) (4)	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '31 Aug 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Aug 2020'	System	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '2020'	System	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:22:01

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:59:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 14:59:19
Data point term sent to Coder	System	06 Nov 2020 14:23:23
User entered 'Seasonal allergies (cough, runny nose)'	Mia Rountree (b) (4)	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'un UNK 1966'	Mia Rountree (b) (4)	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'Jan 1966'	System	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '1966'	System	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:16:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered empty.	System	06 Nov 2020 14:22:40

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '14:20'	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '04 Sep 2020 14:20'	System	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '60.0' in	Mia Rountree (b) (4)	06 Nov 2020 13:49:48
DataPoint set to visible.	System	06 Nov 2020 00:25:26

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '163.0' lb	Mia Rountree (b) (4)	06 Nov 2020 13:49:48
DataPoint set to visible.	System	06 Nov 2020 00:25:26

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered '31.90032'	System	06 Nov 2020 13:49:48
DataPoint set to visible.	System	06 Nov 2020 00:25:26

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'kg/m2'	System	06 Nov 2020 13:49:48
DataPoint set to visible.	System	06 Nov 2020 00:25:26

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'bpm'	System	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'breaths/min'	System	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'mmHg'	System	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User entered 'mmHg'	System	06 Nov 2020 13:49:48

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14

US3912114

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14

US3912114

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:50:08

US3912114

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:50:08

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per DM CLR: Please review date of last menstruation as it does not match to the recorded date in the corresponding MedHistory entry. Reconcile and update as appropriate, otherwise provide clarification. (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 05:48:25
Query 'Per DM CLR: Please review date of last menstruation as it does not match to the recorded date in the corresponding MedHistory entry. Reconcile and update as appropriate, otherwise provide clarification. answered with 'Data has been corrected' (Site from DM).	Mia Rountree (b) (4) (b) (4)	21 Dec 2020 14:41:33
User opened query 'Per DM CLR: Please review date of last menstruation as it does not match to the recorded date in the corresponding MedHistory entry. Reconcile and update as appropriate, otherwise provide clarification. (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:09:28
User entered 'un UNK 2001'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:16:35

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:50:59

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Over 65 years old'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '1'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:46:14
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:53:15

US3912114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 04SEP2020 on Visit 1 Day 1 however the form is not completed in EDC. Kindly review source data and if this sample was collected and submitted, please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 09:37:04
Query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 04SEP2020 on Visit 1 Day 1 however the form is not completed in EDC. Kindly review source data and if this sample was collected and submitted, please update accordingly. Thank you.' answered with 'Data was entered into Nasopharyngeal swab page' (Site from DM).	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:53:42
User opened query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 04SEP2020 on Visit 1 Day 1 however the form is not completed in EDC. Kindly review source data and if this sample was collected and submitted, please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:19:46
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:53:48

US3912114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 4SEP2020 is reported under Visit 1 Day 1visit 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)	26 Nov 2020 09:37:17
User entered '04 Sep 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	06 Nov 2020 14:53:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 4SEP2020 is reported under Visit 1 Day 1visit 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 'Data has been entered into Immunogenicity assessment ' (Site from DM).	Mia Rountree (b) (4)	06 Nov 2020 14:52:53
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 4SEP2020 is reported under Visit 1 Day 1visit 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)	23 Oct 2020 10:46:16
User entered '4 Sep 2020'	Tina Rountree (b) (4)	04 Sep 2020 21:53:48

US3912114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	04 Sep 2020 21:53:48

US3912114

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'VISIT1'	System	04 Sep 2020 21:53:48

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:44:23

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '190045'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:44:23

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 20:44:23

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:25

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:25

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:25

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:25

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:25

US3912114

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Timothy Vachris (b) (4)	03 Oct 2020 13:37:20
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:29:13

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25
	(b) (4)	

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '14:20'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '04 Sep 2020 14:20'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '36.3' C	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '89'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'bpm'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '16'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'breaths/min'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '128'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '69'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered missing code ND - Not Done.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '17:12'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '04 Sep 2020 17:12'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '36.1' C	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: Per CCG V2.0 page 50, Pulse ≥ 101 or ≤ 54 (beats/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:52:13
Query 'Per CDM: Per CCG V2.0 page 50, Pulse ≥ 101 or ≤ 54 (beats/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 23:09:58
User opened query 'Per CDM: Per CCG V2.0 page 50, Pulse ≥ 101 or ≤ 54 (beats/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:59:46
User entered '54'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'bpm'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '16'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'breaths/min'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP > 155 mmHg is considered as grade 3. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:55:43
Query 'Per CDM: Per CCG V2.0 page 50, SBP > 155 mmHg is considered as grade 3. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'Investigator deemed CS, vitals repeated twice still CS. AE was created for hypertension' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 23:11:11
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP > 155 mmHg is considered as grade 3. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:00:05
User entered '159'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	06 Nov 2020 13:55:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '90'	Mia Rountree (b) (4)	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	06 Nov 2020 13:55:25

US3912114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:55:34

US3912114

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:55:34

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Tina Rountree (b) (4)	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Tina Rountree (b) (4)	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format. Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 06:46:45
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format. Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'Data corrected ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:54:22
User entered '04 Sep 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:54:11
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format. Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:06:12
User entered '4 Sep 2020'	Tina Rountree (b) (4) (b) (4)	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '16:25'	Tina Rountree (b) (4)	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '04 Sep 2020 16:25'	System	06 Nov 2020 14:54:11
User entered '4 Sep 2020 16:25'	System	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Right Arm (RIGHT ARM)'	Tina Rountree (b) (4)	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'ONCE'	System	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:54:45

US3912114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:56:02

US3912114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:56:02

US3912114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '15:48'	Mia Rountree (b) (4)	06 Nov 2020 13:56:02

US3912114

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '04 Sep 2020 15:48'	System	06 Nov 2020 13:56:02

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Sep 2020'	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '15:51'	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '04 Sep 2020 15:51'	System	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	06 Nov 2020 13:56:24

US3912114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:59:41

US3912114

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	11 Sep 2020 22:59:41

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:03', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'db22fff4-9ff7-4780-b138-c50dfe8bb3d9' User entered 'Yes (Y)'	System	04 Sep 2020 22:27:30
	System	04 Sep 2020 22:27:30

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:12', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'db22fff4-9ff7-4780-b138-c50dfe8bb3d9' User entered '97.0'	System	04 Sep 2020 22:27:30
	System	04 Sep 2020 22:27:30

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:21', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'db22fff4-9ff7-4780-b138-c50dfe8bb3d9'	System	04 Sep 2020 22:27:30
User entered 'No (N)'	System	04 Sep 2020 22:27:30

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:27', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'db22fff4-9ff7-4780-b138-c50dfe8bb3d9' User entered '04 Sep 2020 17:27'	System	04 Sep 2020 22:27:30
	System	04 Sep 2020 22:27:30

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 16:45'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 19:15'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:54:55', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f15713dd-b12f-4a95-953d-4699db105f9c' User entered 'Yes (Y)'	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:03', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f15713dd-b12f-4a95-953d-4699db105f9c' User entered '97.3'	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:09', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f15713dd-b12f-4a95-953d-4699db105f9c' User entered 'Yes (Y)'	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
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 'Confirmed and added to con meds' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 07:40:46
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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f15713dd-b12f-4a95-953d-4699db105f9c' User entered '1'	Timothy Vachris (b) (4) (b) (4)	03 Oct 2020 13:39:27
	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f15713dd-b12f-4a95-953d-4699db105f9c' User entered '0'	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:26', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f15713dd-b12f-4a95-953d-4699db105f9c' User entered '04 Sep 2020 20:55'	System	05 Sep 2020 01:55:31
	System	05 Sep 2020 01:55:31

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 20:10'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 2'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:24', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4' User entered 'Yes (Y)'	System	06 Sep 2020 00:59:53
	System	06 Sep 2020 00:59:53

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:32', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4' User entered '97.8'	System	06 Sep 2020 00:59:53
	System	06 Sep 2020 00:59:53

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:37', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4'	System	06 Sep 2020 00:59:53
User entered 'Yes (Y)'	System	06 Sep 2020 00:59:53

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
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 'Con meds updated' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 07:13:01
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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4' User entered '1'	Tina Rountree (b) (4) (b) (4)	08 Oct 2020 20:58:45
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).	System	06 Sep 2020 00:59:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4' User entered '1'	System	06 Sep 2020 00:59:53
User entered '1'	System	06 Sep 2020 00:59:53

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4' User entered '0'	System	06 Sep 2020 00:59:53
	System	06 Sep 2020 00:59:53

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:49', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '22368417-540c-4078-9815-86405424a3c4' User entered '05 Sep 2020 19:59'	System	06 Sep 2020 00:59:53
	System	06 Sep 2020 00:59:53

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 3'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:13:27', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a328e5ce-7f8f-4b22-b401-1d73846f4f82'	System	06 Sep 2020 21:13:54
User entered 'Yes (Y)'	System	06 Sep 2020 21:13:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:13:34', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a328e5ce-7f8f-4b22-b401-1d73846f4f82' User entered '97.8'	System	06 Sep 2020 21:13:54
	System	06 Sep 2020 21:13:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:13:40', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a328e5ce-7f8f-4b22-b401-1d73846f4f82'	System	06 Sep 2020 21:13:54
User entered 'No (N)'	System	06 Sep 2020 21:13:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:13:50', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a328e5ce-7f8f-4b22-b401-1d73846f4f82'	System	06 Sep 2020 21:13:54
User entered '06 Sep 2020 16:13'	System	06 Sep 2020 21:13:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 4'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:21:27', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6fa7e384-7d68-4ed5-a50a-a21bcf3e750c' User entered 'Yes (Y)'	System	07 Sep 2020 20:21:54
	System	07 Sep 2020 20:21:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:21:40', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6fa7e384-7d68-4ed5-a50a-a21bcf3e750c' User entered '98.7'	System	07 Sep 2020 20:21:54
	System	07 Sep 2020 20:21:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:21:44', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6fa7e384-7d68-4ed5-a50a-a21bcf3e750c'	System	07 Sep 2020 20:21:54
User entered 'No (N)'	System	07 Sep 2020 20:21:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:21:50', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6fa7e384-7d68-4ed5-a50a-a21bcf3e750c'	System	07 Sep 2020 20:21:54
User entered '07 Sep 2020 15:21'	System	07 Sep 2020 20:21:54

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 5'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:35:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a18c8567-bad6-458d-b306-d84114053fb3' User entered 'Yes (Y)'	System	08 Sep 2020 21:36:00
	System	08 Sep 2020 21:36:00

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:35:50', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a18c8567-bad6-458d-b306-d84114053fb3' User entered '97.2'	System	08 Sep 2020 21:36:00
	System	08 Sep 2020 21:36:00

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:35:53', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a18c8567-bad6-458d-b306-d84114053fb3' User entered 'No (N)'	System	08 Sep 2020 21:36:00
	System	08 Sep 2020 21:36:00

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:35:58', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a18c8567-bad6-458d-b306-d84114053fb3' User entered '08 Sep 2020 16:35'	System	08 Sep 2020 21:36:00
	System	08 Sep 2020 21:36:00

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 6'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:21', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '309e826a-e9eb-4cff-addb-1acdd8f4e7a3' User entered 'Yes (Y)'	System	10 Sep 2020 00:33:44
	System	10 Sep 2020 00:33:44

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:31', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '309e826a-e9eb-4cff-addb-1acdd8f4e7a3' User entered '98.7'	System	10 Sep 2020 00:33:44
	System	10 Sep 2020 00:33:44

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:34', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '309e826a-e9eb-4cff-addb-1acdd8f4e7a3'	System	10 Sep 2020 00:33:44
User entered 'No (N)'	System	10 Sep 2020 00:33:44

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:39', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '309e826a-e9eb-4cff-addb-1acdd8f4e7a3' User entered '09 Sep 2020 19:33'	System	10 Sep 2020 00:33:44
	System	10 Sep 2020 00:33:44

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 7'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '00e678b6-a9d8-4ed2-b6ab-e1a90287c483' User entered 'Yes (Y)'	System	11 Sep 2020 01:05:40
	System	11 Sep 2020 01:05:40

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:24', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '00e678b6-a9d8-4ed2-b6ab-e1a90287c483' User entered '97.0'	System	11 Sep 2020 01:05:40
	System	11 Sep 2020 01:05:40

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:31', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '00e678b6-a9d8-4ed2-b6ab-e1a90287c483'	System	11 Sep 2020 01:05:40
User entered 'No (N)'	System	11 Sep 2020 01:05:40

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:35', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '00e678b6-a9d8-4ed2-b6ab-e1a90287c483' User entered '10 Sep 2020 20:05'	System	11 Sep 2020 01:05:40
	System	11 Sep 2020 01:05:40

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:41', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '40b69eff-1655-4bd7-91a8-4b2d4dc4521e' User entered 'None (1)'	System	04 Sep 2020 22:28:02
	System	04 Sep 2020 22:28:02

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:46', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '40b69eff-1655-4bd7-91a8-4b2d4dc4521e' User entered 'No (N)'	System	04 Sep 2020 22:28:02
	System	04 Sep 2020 22:28:02

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:50', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '40b69eff-1655-4bd7-91a8-4b2d4dc4521e' User entered 'No (N)'	System	04 Sep 2020 22:28:02
	System	04 Sep 2020 22:28:02

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:27:54', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '40b69eff-1655-4bd7-91a8-4b2d4dc4521e' User entered 'None (1)'	System	04 Sep 2020 22:28:02
	System	04 Sep 2020 22:28:02

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '40b69eff-1655-4bd7-91a8-4b2d4dc4521e' User entered '04 Sep 2020 17:28'	System	04 Sep 2020 22:28:02
	System	04 Sep 2020 22:28:02

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 16:45'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 19:15'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:36', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '64096db0-bc95-43c4-891d-bbdc949c655'	System	05 Sep 2020 01:56:23
User entered 'None (1)'	System	05 Sep 2020 01:56:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:55:57', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '64096db0-bc95-43c4-891d-bbdc949c655'	System	05 Sep 2020 01:56:23
User entered 'No (N)'	System	05 Sep 2020 01:56:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '64096db0-bc95-43c4-891d-bbdc949c655'	System	05 Sep 2020 01:56:23
User entered 'No (N)'	System	05 Sep 2020 01:56:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:13', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '64096db0-bc95-43c4-891d-bbdc949c655'	System	05 Sep 2020 01:56:23
User entered 'None (1)'	System	05 Sep 2020 01:56:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:21', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '64096db0-bc95-43c4-891d-bbdc949c655'	System	05 Sep 2020 01:56:23
User entered '04 Sep 2020 20:56'	System	05 Sep 2020 01:56:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 20:10'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 2'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T19:59:59', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '60b5010d-bc4e-43b6-b03e-906b43711bf3' User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 01:00:27
	System	06 Sep 2020 01:00:27

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:02', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '60b5010d-bc4e-43b6-b03e-906b43711bf3' User entered 'No (N)'	System	06 Sep 2020 01:00:27
	System	06 Sep 2020 01:00:27

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:08', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '60b5010d-bc4e-43b6-b03e-906b43711bf3' User entered 'No (N)'	System	06 Sep 2020 01:00:27
	System	06 Sep 2020 01:00:27

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '60b5010d-bc4e-43b6-b03e-906b43711bf3' User entered 'None (1)'	System	06 Sep 2020 01:00:27
	System	06 Sep 2020 01:00:27

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:24', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '60b5010d-bc4e-43b6-b03e-906b43711bf3' User entered '05 Sep 2020 20:00'	System	06 Sep 2020 01:00:27
	System	06 Sep 2020 01:00:27

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 3'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:03', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd283cb67-9aaa-4612-a33b-74cb182d7b9d'	System	06 Sep 2020 21:14:44
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 21:14:44

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:07', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd283cb67-9aaa-4612-a33b-74cb182d7b9d' User entered 'No (N)'	System	06 Sep 2020 21:14:44
	System	06 Sep 2020 21:14:44

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd283cb67-9aaa-4612-a33b-74cb182d7b9d'	System	06 Sep 2020 21:14:44
User entered 'No (N)'	System	06 Sep 2020 21:14:44

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:29', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd283cb67-9aaa-4612-a33b-74cb182d7b9d' User entered 'None (1)'	System	06 Sep 2020 21:14:44
	System	06 Sep 2020 21:14:44

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:42', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd283cb67-9aaa-4612-a33b-74cb182d7b9d' User entered '06 Sep 2020 16:14'	System	06 Sep 2020 21:14:44
	System	06 Sep 2020 21:14:44

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 4'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:21:59', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7db4fc2e-ae33-49d0-82ff-d87d4937af10'	System	07 Sep 2020 20:22:23
User entered 'None (1)'	System	07 Sep 2020 20:22:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:03', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7db4fc2e-ae33-49d0-82ff-d87d4937af10'	System	07 Sep 2020 20:22:23
User entered 'No (N)'	System	07 Sep 2020 20:22:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:07', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7db4fc2e-ae33-49d0-82ff-d87d4937af10'	System	07 Sep 2020 20:22:23
User entered 'No (N)'	System	07 Sep 2020 20:22:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:15', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7db4fc2e-ae33-49d0-82ff-d87d4937af10'	System	07 Sep 2020 20:22:23
User entered 'None (1)'	System	07 Sep 2020 20:22:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:22', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7db4fc2e-ae33-49d0-82ff-d87d4937af10'	System	07 Sep 2020 20:22:23
User entered '07 Sep 2020 15:22'	System	07 Sep 2020 20:22:23

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 5'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:04', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '1d5e1527-84ef-4222-b402-352c18105425'	System	08 Sep 2020 21:36:32
User entered 'None (1)'	System	08 Sep 2020 21:36:32

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:07', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '1d5e1527-84ef-4222-b402-352c18105425' User entered 'No (N)'	System	08 Sep 2020 21:36:32
	System	08 Sep 2020 21:36:32

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:14', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '1d5e1527-84ef-4222-b402-352c18105425' User entered 'No (N)'	System	08 Sep 2020 21:36:32
	System	08 Sep 2020 21:36:32

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:24', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '1d5e1527-84ef-4222-b402-352c18105425' User entered 'None (1)'	System	08 Sep 2020 21:36:32
	System	08 Sep 2020 21:36:32

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:28', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '1d5e1527-84ef-4222-b402-352c18105425' User entered '08 Sep 2020 16:36'	System	08 Sep 2020 21:36:32
	System	08 Sep 2020 21:36:32

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 6'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:44', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a6747eb3-fd55-4b10-9df5-2cd48cf8d592'	System	10 Sep 2020 00:34:05
User entered 'None (1)'	System	10 Sep 2020 00:34:05

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:48', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a6747eb3-fd55-4b10-9df5-2cd48cf8d592'	System	10 Sep 2020 00:34:05
User entered 'No (N)'	System	10 Sep 2020 00:34:05

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:51', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a6747eb3-fd55-4b10-9df5-2cd48cf8d592'	System	10 Sep 2020 00:34:05
User entered 'No (N)'	System	10 Sep 2020 00:34:05

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:33:58', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a6747eb3-fd55-4b10-9df5-2cd48cf8d592'	System	10 Sep 2020 00:34:05
User entered 'None (1)'	System	10 Sep 2020 00:34:05

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:02', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a6747eb3-fd55-4b10-9df5-2cd48cf8d592'	System	10 Sep 2020 00:34:05
User entered '09 Sep 2020 19:34'	System	10 Sep 2020 00:34:05

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 7'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:42', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd71e9ad2-a3c5-4cee-bc6c-2582a5e44baf' User entered 'None (1)'	System	11 Sep 2020 01:06:14
	System	11 Sep 2020 01:06:14

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:45', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd71e9ad2-a3c5-4cee-bc6c-2582a5e44baf' User entered 'No (N)'	System	11 Sep 2020 01:06:14
	System	11 Sep 2020 01:06:14

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:48', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd71e9ad2-a3c5-4cee-bc6c-2582a5e44baf' User entered 'No (N)'	System	11 Sep 2020 01:06:14
	System	11 Sep 2020 01:06:14

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:54', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd71e9ad2-a3c5-4cee-bc6c-2582a5e44baf' User entered 'None (1)'	System	11 Sep 2020 01:06:14
	System	11 Sep 2020 01:06:14

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:05:58', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd71e9ad2-a3c5-4cee-bc6c-2582a5e44baf' User entered '10 Sep 2020 20:05'	System	11 Sep 2020 01:06:14
	System	11 Sep 2020 01:06:14

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:09', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'None (0)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:13', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'None (0)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:16', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'None (0)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:20', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'None (0)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:23', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'None (0)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:26', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'None (0)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:32', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered 'No (N)'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T17:28:35', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '43250ccf-dede-4689-83dc-e11cef2d1967'	System	04 Sep 2020 22:28:40
User entered '04 Sep 2020 17:28'	System	04 Sep 2020 22:28:40

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 16:45'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 19:15'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:31', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b'	System	05 Sep 2020 01:57:14
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:38', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered 'None (0)'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:41', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered 'None (0)'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:44', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered 'None (0)'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:48', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered 'None (0)'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:56:57', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered 'None (0)'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:57:03', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered 'No (N)'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-04T20:57:11', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c639dabf-bfe1-48c3-a842-a79bad2a9e3b' User entered '04 Sep 2020 20:57'	System	05 Sep 2020 01:57:14
	System	05 Sep 2020 01:57:14

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '04 Sep 2020 20:10'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 2'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:36', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093'	System	06 Sep 2020 01:01:05
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:40', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered 'None (0)'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered 'None (0)'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:46', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered 'None (0)'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:48', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered 'None (0)'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:51', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered 'None (0)'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:00:55', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered 'No (N)'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-05T20:01:01', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a1abaeb3-046e-4462-931a-b3c396085093' User entered '05 Sep 2020 20:01'	System	06 Sep 2020 01:01:05
	System	06 Sep 2020 01:01:05

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 3'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:50', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9'	System	06 Sep 2020 21:15:22
User entered 'No interference with activity (1)'	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:54', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9' User entered 'None (0)'	System	06 Sep 2020 21:15:22
	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:14:58', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9' User entered 'None (0)'	System	06 Sep 2020 21:15:22
	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:15:02', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9' User entered 'None (0)'	System	06 Sep 2020 21:15:22
	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:15:04', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9' User entered 'None (0)'	System	06 Sep 2020 21:15:22
	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:15:09', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9' User entered 'None (0)'	System	06 Sep 2020 21:15:22
	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:15:12', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9' User entered 'No (N)'	System	06 Sep 2020 21:15:22
	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-06T16:15:20', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ed7ef0e8-2972-4e99-8b2e-52f3631ae3d9'	System	06 Sep 2020 21:15:22
User entered '06 Sep 2020 16:15'	System	06 Sep 2020 21:15:22

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 4'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:30', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82' User entered 'None (0)'	System	07 Sep 2020 20:23:03
	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:34', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82'	System	07 Sep 2020 20:23:03
User entered 'None (0)'	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:37', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82'	System	07 Sep 2020 20:23:03
User entered 'None (0)'	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82' User entered 'None (0)'	System	07 Sep 2020 20:23:03
	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:49', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82' User entered 'None (0)'	System	07 Sep 2020 20:23:03
	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:52', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82' User entered 'None (0)'	System	07 Sep 2020 20:23:03
	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:22:58', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82'	System	07 Sep 2020 20:23:03
User entered 'No (N)'	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-07T15:23:02', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '18fa3ae7-5568-4689-92e3-0e19c2a9ef82'	System	07 Sep 2020 20:23:03
User entered '07 Sep 2020 15:23'	System	07 Sep 2020 20:23:03

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 5'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:34', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'None (0)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:36', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'None (0)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:39', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'None (0)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:41', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'None (0)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:44', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'None (0)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:45', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'None (0)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:48', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered 'No (N)'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-08T16:36:54', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '809cc980-a7bf-471a-a1e6-e60d57d79bca' User entered '08 Sep 2020 16:36'	System	08 Sep 2020 21:36:55
	System	08 Sep 2020 21:36:55

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 6'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:09', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'None (0)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:13', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'None (0)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'None (0)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:20', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'None (0)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:23', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'None (0)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:26', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'None (0)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:30', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered 'No (N)'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-09T19:34:35', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'adc813f5-1e28-41f1-af6d-d5cc07cd2786' User entered '09 Sep 2020 19:34'	System	10 Sep 2020 00:34:36
	System	10 Sep 2020 00:34:36

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 7'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:03', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'None (0)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:06', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'None (0)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:09', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'None (0)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:11', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'None (0)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:18', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'None (0)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:23', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'None (0)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:34', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered 'No (N)'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-09-10T20:06:38', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '24d9d007-f8e3-4f3b-bee3-8e5f712b3681' User entered '10 Sep 2020 20:06'	System	11 Sep 2020 01:06:41
	System	11 Sep 2020 01:06:41

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:54:45

US3912114

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 23:00:15

US3912114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 23:00:15

US3912114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 23:00:15

US3912114

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 23:00:15

US3912114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	18 Sep 2020 22:25:41

US3912114

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	18 Sep 2020 22:25:41

US3912114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	18 Sep 2020 22:25:58

US3912114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit 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)	27 Nov 2020 07:07:10
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit 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 'Data has been entered' (Site from DM).	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 22:37:55
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit 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)	23 Oct 2020 09:27:06
User entered '18 Sep 2020'	Monique Gawlik (b) (4)	18 Sep 2020 22:25:58

US3912114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	18 Sep 2020 22:25:58

US3912114

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4)	18 Sep 2020 22:25:58
	Monique Gawlik (b) (4)	

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Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	18 Sep 2020 22:26:07

US3912114

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	18 Sep 2020 22:26:07

US3912114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'No (N)'	Mia Rountree (b) (4)	23 Oct 2020 18:39:33

US3912114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:39:33

US3912114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Query 'Per eCRF Guidelines v5.0 Page 46, please indicate 'Contact Not Made'. Thank you!' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:48:12
User opened query 'Per eCRF Guidelines v5.0 Page 46, please indicate 'Contact Not Made'. Thank you!' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 19:46:38
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:39:33

US3912114

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User closed query 'Per eCRF guidelines v2.0, Page 33: If contact was not made Please provide reason in comment section.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:11
Query 'Per eCRF guidelines v2.0, Page 33: If contact was not made Please provide reason in comment section.' answered with 'comment provided' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:23:36
User entered 'reason for missed safety call is unknown.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:23:26
User opened query 'Per eCRF guidelines v2.0, Page 33: If contact was not made Please provide reason in comment section.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 16:05:12
User entered empty.	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:39:33

US3912114

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:39:42

US3912114

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	23 Oct 2020 18:39:42

US3912114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: V2D29 visit was performed to the patient and "EXPOSURE" form is blank, please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 11:08:59
Query 'Per CDM: V2D29 visit was performed to the patient and "EXPOSURE" form is blank, please review and update accordingly.' answered with 'Exposure form has been filled out ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 13:59:12
User opened query 'Per CDM: V2D29 visit was performed to the patient and "EXPOSURE" form is blank, please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:08:22
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:40:58

US3912114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:40:58

US3912114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	23 Oct 2020 18:40:58

US3912114

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'VISIT2'	System	23 Oct 2020 18:40:58

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '11:20'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '02 Oct 2020 11:20'	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '36.4' C	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '75'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'bpm'	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '16'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'breaths/min'	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:56:24
Query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 23:12:13
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:02:08
User entered '146'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '85'	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User closed query 'Per CDM: Were vital signs assessed? is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 23:55:38
Query 'Per CDM: Were vital signs assessed? is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you.' answered with 'Subject was not dosed due to Inc #7 at screening' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 23:13:30
User opened query 'Per CDM: Were vital signs assessed? is recorded as 'No', however, per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection. Please clarify and update as appropriate Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:02:41
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	23 Oct 2020 18:43:36

US3912114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:44:08

US3912114

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:44:08

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Subject did not meet I/E at screening so the decision was made not to dose her again.'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	30 Oct 2020 18:29:33

US3912114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:45:17

US3912114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:45:17

US3912114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '12:00'	Mia Rountree (b) (4)	23 Oct 2020 18:45:17

US3912114

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '02 Oct 2020 12:00'	System	23 Oct 2020 18:45:17

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '02 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '12:05'	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '02 Oct 2020 12:05'	System	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'No (N)'	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered empty.	System	23 Oct 2020 18:45:39

US3912114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:48:37

US3912114

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	23 Oct 2020 18:48:37

US3912114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:49:08

US3912114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '09 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:49:08

US3912114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	23 Oct 2020 18:49:08

US3912114

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:49:08

US3912114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:49:14

US3912114

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	23 Oct 2020 18:49:14

US3912114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:49:58

US3912114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '16 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:49:58

US3912114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	23 Oct 2020 18:49:58

US3912114

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:49:58

US3912114

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:50:03

US3912114

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	23 Oct 2020 18:50:03

US3912114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:50:24

US3912114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '23 Oct 2020'	Mia Rountree (b) (4)	23 Oct 2020 18:50:24

US3912114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	23 Oct 2020 18:50:24

US3912114

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	23 Oct 2020 18:50:24

US3912114

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	Mia Rountree (b) (4)	23 Oct 2020 18:50:29

US3912114

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	23 Oct 2020 18:50:29

US3912114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:00:04

US3912114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Nov 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:00:04

US3912114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	06 Nov 2020 14:00:04

US3912114

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'VISIT3'	System	06 Nov 2020 14:00:04

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Nov 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '12:23'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '04 Nov 2020 12:23'	System	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '36.3' C	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '79'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'bpm'	System	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '14'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'breaths/min'	System	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '139'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '85'	Mia Rountree (b) (4)	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered 'mmHg'	System	06 Nov 2020 14:00:43

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23

US3912114

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23

US3912114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:01:01

US3912114

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '04 Nov 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:01:01

US3912114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:01:18

US3912114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '4 Nov 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:01:18

US3912114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered '13:04'	Mia Rountree (b) (4)	06 Nov 2020 14:01:18

US3912114

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '4 Nov 2020 13:04'	System	06 Nov 2020 14:01:18

US3912114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:54
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:01:23

US3912114

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	06 Nov 2020 14:01:23

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 64'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-04T12:28:53', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '231af877-5ba3-4aa8-b155-b60993da3320' User entered 'No (N)'	System	04 Nov 2020 18:29:06
	System	04 Nov 2020 18:29:06

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-04T12:28:58', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '231af877-5ba3-4aa8-b155-b60993da3320'	System	04 Nov 2020 18:29:06
User entered 'No (N)'	System	04 Nov 2020 18:29:06

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-04T12:29:04', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '231af877-5ba3-4aa8-b155-b60993da3320' User entered '04 Nov 2020 12:29:04'	System	04 Nov 2020 18:29:06
	System	04 Nov 2020 18:29:06

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 71'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-14T17:59:47', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ec401a92-dc28-4eb7-8b7f-127d999c8ce5' User entered 'No (N)'	System	15 Nov 2020 00:00:08
	System	15 Nov 2020 00:00:08

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-14T17:59:55', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ec401a92-dc28-4eb7-8b7f-127d999c8ce5'	System	15 Nov 2020 00:00:08
User entered 'No (N)'	System	15 Nov 2020 00:00:08

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-14T18:00:02', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ec401a92-dc28-4eb7-8b7f-127d999c8ce5'	System	15 Nov 2020 00:00:08
User entered '14 Nov 2020 18:00:02'	System	15 Nov 2020 00:00:08

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered 'Day 78'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-18T08:13:50', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f110c775-fa1b-4115-a936-3d70e4e5cd84' User entered 'No (N)'	System	18 Nov 2020 14:14:08
	System	18 Nov 2020 14:14:08

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-18T08:13:57', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f110c775-fa1b-4115-a936-3d70e4e5cd84'	System	18 Nov 2020 14:14:08
User entered 'No (N)'	System	18 Nov 2020 14:14:08

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-18T08:14:06', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'f110c775-fa1b-4115-a936-3d70e4e5cd84' User entered '18 Nov 2020 08:14:06'	System	18 Nov 2020 14:14:08
	System	18 Nov 2020 14:14:08

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 21:54:45

US3912114

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:14:25
Data entry locked.	System	04 Sep 2020 21:54:45
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 21:54:45

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-26T17:43:10', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '13ffe1cb-de58-47fd-a120-507bbfcbe09c'	System	26 Nov 2020 23:43:27
User entered 'No (N)'	System	26 Nov 2020 23:43:27

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-26T17:43:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '13ffe1cb-de58-47fd-a120-507bbfcbe09c'	System	26 Nov 2020 23:43:27
User entered 'No (N)'	System	26 Nov 2020 23:43:27

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-26T17:43:25', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '13ffe1cb-de58-47fd-a120-507bbfcbe09c' User entered '26 Nov 2020 17:43:25'	System	26 Nov 2020 23:43:27
	System	26 Nov 2020 23:43:27

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-29T08:27:37', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a78f1b0d-1262-46f3-85af-0c375646a4e1'	System	29 Nov 2020 14:27:59
User entered 'No (N)'	System	29 Nov 2020 14:27:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-29T08:27:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a78f1b0d-1262-46f3-85af-0c375646a4e1'	System	29 Nov 2020 14:27:59
User entered 'No (N)'	System	29 Nov 2020 14:27:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-11-29T08:27:54', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a78f1b0d-1262-46f3-85af-0c375646a4e1' User entered '29 Nov 2020 08:27:54'	System	29 Nov 2020 14:27:59
	System	29 Nov 2020 14:27:59

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-06T06:55:11', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'cc572566-9a8e-4737-828b-cc7e0844a5b6'	System	06 Dec 2020 12:55:27
User entered 'No (N)'	System	06 Dec 2020 12:55:27

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-06T06:55:19', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'cc572566-9a8e-4737-828b-cc7e0844a5b6'	System	06 Dec 2020 12:55:27
User entered 'No (N)'	System	06 Dec 2020 12:55:27

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-06T06:55:25', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'cc572566-9a8e-4737-828b-cc7e0844a5b6' User entered '06 Dec 2020 06:55:25'	System	06 Dec 2020 12:55:27
	System	06 Dec 2020 12:55:27

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-13T10:19:55', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6c1c253b-e02e-4a15-a867-991188e4fe49' User entered 'No (N)'	System	13 Dec 2020 16:20:20
	System	13 Dec 2020 16:20:20

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-13T10:20:09', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6c1c253b-e02e-4a15-a867-991188e4fe49' User entered 'No (N)'	System	13 Dec 2020 16:20:20
	System	13 Dec 2020 16:20:20

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-13T10:20:15', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '6c1c253b-e02e-4a15-a867-991188e4fe49' User entered '13 Dec 2020 10:20:15'	System	13 Dec 2020 16:20:20
	System	13 Dec 2020 16:20:20

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-20T17:23:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'eb998205-4544-4158-85aa-8e65afeeafa8'	System	20 Dec 2020 23:23:28
User entered 'No (N)'	System	20 Dec 2020 23:23:28

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-20T17:23:22', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'eb998205-4544-4158-85aa-8e65afeeafa8'	System	20 Dec 2020 23:23:28
User entered 'No (N)'	System	20 Dec 2020 23:23:28

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-20T17:23:27', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'eb998205-4544-4158-85aa-8e65afeeafa8' User entered '20 Dec 2020 17:23:27'	System	20 Dec 2020 23:23:28
	System	20 Dec 2020 23:23:28

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-27T19:55:27', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7b290d56-ced0-48af-bce7-94c045d51235'	System	28 Dec 2020 01:55:41
User entered 'No (N)'	System	28 Dec 2020 01:55:41

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-27T19:55:32', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7b290d56-ced0-48af-bce7-94c045d51235'	System	28 Dec 2020 01:55:41
User entered 'No (N)'	System	28 Dec 2020 01:55:41

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2020-12-27T19:55:38', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7b290d56-ced0-48af-bce7-94c045d51235' User entered '27 Dec 2020 19:55:38'	System	28 Dec 2020 01:55:41
	System	28 Dec 2020 01:55:41

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-03T06:11:26', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'b5451e9c-9087-4169-9274-d3af6630f63e'	System	03 Jan 2021 12:11:47
User entered 'No (N)'	System	03 Jan 2021 12:11:47

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-03T06:11:37', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'b5451e9c-9087-4169-9274-d3af6630f63e' User entered 'No (N)'	System	03 Jan 2021 12:11:47

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-03T06:11:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'b5451e9c-9087-4169-9274-d3af6630f63e' User entered '03 Jan 2021 06:11:43'	System	03 Jan 2021 12:11:47
	System	03 Jan 2021 12:11:47

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-10T06:07:06', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ce042667-d7f6-42e5-989b-7c84a8f69a1b'	System	10 Jan 2021 12:07:20
User entered 'No (N)'	System	10 Jan 2021 12:07:20

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-10T06:07:12', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ce042667-d7f6-42e5-989b-7c84a8f69a1b' User entered 'No (N)'	System	10 Jan 2021 12:07:20

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-10T06:07:17', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'ce042667-d7f6-42e5-989b-7c84a8f69a1b' User entered '10 Jan 2021 06:07:17'	System	10 Jan 2021 12:07:20
	System	10 Jan 2021 12:07:20

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-17T07:10:36', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '17674507-f84c-43da-a9de-e0c1d5c815f8'	System	17 Jan 2021 13:10:52
User entered 'No (N)'	System	17 Jan 2021 13:10:52

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-17T07:10:43', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '17674507-f84c-43da-a9de-e0c1d5c815f8'	System	17 Jan 2021 13:10:52
User entered 'No (N)'	System	17 Jan 2021 13:10:52

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-17T07:10:49', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '17674507-f84c-43da-a9de-e0c1d5c815f8' User entered '17 Jan 2021 07:10:49'	System	17 Jan 2021 13:10:52
	System	17 Jan 2021 13:10:52

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-26T20:50:04', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '5cac0ac9-fa94-46ac-8e5c-c8122545e43b'	System	27 Jan 2021 02:50:15
User entered 'No (N)'	System	27 Jan 2021 02:50:15

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-26T20:50:08', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '5cac0ac9-fa94-46ac-8e5c-c8122545e43b'	System	27 Jan 2021 02:50:15
User entered 'No (N)'	System	27 Jan 2021 02:50:15

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-01-26T20:50:12', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '5cac0ac9-fa94-46ac-8e5c-c8122545e43b' User entered '26 Jan 2021 20:50:12'	System	27 Jan 2021 02:50:15
	System	27 Jan 2021 02:50:15

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-02T12:45:13', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '0284fd88-5642-4020-af5c-295210532cef'	System	02 Feb 2021 19:01:53
User entered 'No (N)'	System	02 Feb 2021 19:01:53

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-02T12:45:18', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '0284fd88-5642-4020-af5c-295210532cef' User entered 'No (N)'	System	02 Feb 2021 19:01:53

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-02T12:45:23', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '0284fd88-5642-4020-af5c-295210532cef' User entered '02 Feb 2021 12:45:23'	System	02 Feb 2021 19:01:53
	System	02 Feb 2021 19:01:53

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-07T07:19:46', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd0f38edb-92ff-4283-8c45-792d98e923e2'	System	07 Feb 2021 13:20:01
User entered 'No (N)'	System	07 Feb 2021 13:20:01

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-07T07:19:53', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd0f38edb-92ff-4283-8c45-792d98e923e2'	System	07 Feb 2021 13:20:01
User entered 'No (N)'	System	07 Feb 2021 13:20:01

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-07T07:19:57', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'd0f38edb-92ff-4283-8c45-792d98e923e2' User entered '07 Feb 2021 07:19:57'	System	07 Feb 2021 13:20:01
	System	07 Feb 2021 13:20:01

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-17T18:23:59', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '93c346c1-2553-411c-91fd-dfbcfee4da8f' User entered 'No (N)'	System	18 Feb 2021 00:24:15
	System	18 Feb 2021 00:24:15

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-17T18:24:06', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '93c346c1-2553-411c-91fd-dfbcfee4da8f' User entered 'No (N)'	System	18 Feb 2021 00:24:15
	System	18 Feb 2021 00:24:15

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-17T18:24:11', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '93c346c1-2553-411c-91fd-dfbcfee4da8f' User entered '17 Feb 2021 18:24:11'	System	18 Feb 2021 00:24:15
	System	18 Feb 2021 00:24:15

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-21T07:02:26', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'e8a4f20a-b786-47a1-bd40-c1ea4844b03b' User entered 'No (N)'	System	21 Feb 2021 13:02:34

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-21T07:02:22', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'e8a4f20a-b786-47a1-bd40-c1ea4844b03b'	System	21 Feb 2021 13:02:34
User entered 'No (N)'	System	21 Feb 2021 13:02:34

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-21T07:02:31', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'e8a4f20a-b786-47a1-bd40-c1ea4844b03b' User entered '21 Feb 2021 07:02:31'	System	21 Feb 2021 13:02:34
	System	21 Feb 2021 13:02:34

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-28T07:22:39-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '81e0f474-d3c0-4428-928b-c5a886538139'	System	28 Feb 2021 13:22:53
User entered 'No (N)'	System	28 Feb 2021 13:22:53

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-28T07:22:44-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '81e0f474-d3c0-4428-928b-c5a886538139'	System	28 Feb 2021 13:22:53
User entered 'No (N)'	System	28 Feb 2021 13:22:53

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-28T07:22:48-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '81e0f474-d3c0-4428-928b-c5a886538139'	System	28 Feb 2021 13:22:53
User entered '28 Feb 2021 13:22:48'	System	28 Feb 2021 13:22:53

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-09T12:03:02-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'e3e6664d-f9ef-4b46-9c93-c8cd538df830'	System	09 Mar 2021 18:06:58
User entered 'No (N)'	System	09 Mar 2021 18:06:58

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-09T12:03:07-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'e3e6664d-f9ef-4b46-9c93-c8cd538df830'	System	09 Mar 2021 18:06:58
User entered 'No (N)'	System	09 Mar 2021 18:06:58

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-09T12:03:11-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'e3e6664d-f9ef-4b46-9c93-c8cd538df830'	System	09 Mar 2021 18:06:58
User entered '09 Mar 2021 12:03:11'	System	09 Mar 2021 18:06:58

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-14T16:29:43-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '435d6a74-dee3-4a6c-b4d0-a41743bf52a5'	System	14 Mar 2021 21:29:54
User entered 'No (N)'	System	14 Mar 2021 21:29:54

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-14T16:29:47-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '435d6a74-dee3-4a6c-b4d0-a41743bf52a5'	System	14 Mar 2021 21:29:54
User entered 'No (N)'	System	14 Mar 2021 21:29:54

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-14T16:29:53-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '435d6a74-dee3-4a6c-b4d0-a41743bf52a5'	System	14 Mar 2021 21:29:54
User entered '14 Mar 2021 16:29:53'	System	14 Mar 2021 21:29:54

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-23T12:00:15-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a12f4283-340c-4505-9eb4-6586688704d0'	System	23 Mar 2021 17:00:36
User entered 'No (N)'	System	23 Mar 2021 17:00:36

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-23T12:00:19-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a12f4283-340c-4505-9eb4-6586688704d0'	System	23 Mar 2021 17:00:36
User entered 'No (N)'	System	23 Mar 2021 17:00:36

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-23T12:00:22-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'a12f4283-340c-4505-9eb4-6586688704d0'	System	23 Mar 2021 17:00:36
User entered '23 Mar 2021 12:00:22'	System	23 Mar 2021 17:00:36

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-28T06:13:28-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c4514962-e168-4558-9e2d-10a07e599d91'	System	28 Mar 2021 11:13:46
User entered 'No (N)'	System	28 Mar 2021 11:13:46

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-28T06:13:38-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c4514962-e168-4558-9e2d-10a07e599d91'	System	28 Mar 2021 11:13:46
User entered 'No (N)'	System	28 Mar 2021 11:13:46

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-03-28T06:13:44-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c4514962-e168-4558-9e2d-10a07e599d91' User entered '28 Mar 2021 06:13:44'	System	28 Mar 2021 11:13:46
	System	28 Mar 2021 11:13:46

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-04T08:41:14-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '328615a9-5271-40fb-9a3e-6b3720de1992'	System	04 Apr 2021 13:41:24
User entered 'No (N)'	System	04 Apr 2021 13:41:24

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-04T08:41:17-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '328615a9-5271-40fb-9a3e-6b3720de1992'	System	04 Apr 2021 13:41:24
User entered 'No (N)'	System	04 Apr 2021 13:41:24

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-04T08:41:21-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '328615a9-5271-40fb-9a3e-6b3720de1992'	System	04 Apr 2021 13:41:24
User entered '04 Apr 2021 08:41:21'	System	04 Apr 2021 13:41:24

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-11T07:21:22-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '2d1f2a62-4c04-4379-94bc-24090a2e715e'	System	11 Apr 2021 12:21:36
User entered 'No (N)'	System	11 Apr 2021 12:21:36

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-11T07:21:26-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '2d1f2a62-4c04-4379-94bc-24090a2e715e'	System	11 Apr 2021 12:21:36
User entered 'No (N)'	System	11 Apr 2021 12:21:36

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-11T07:21:32-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '2d1f2a62-4c04-4379-94bc-24090a2e715e' User entered '11 Apr 2021 07:21:32'	System	11 Apr 2021 12:21:36
	System	11 Apr 2021 12:21:36

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-18T13:07:28-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'b2e98dd2-8661-4c38-ae00-b7bfb535316a' User entered 'No (N)'	System	18 Apr 2021 18:07:38
	System	18 Apr 2021 18:07:38

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-18T13:07:33-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'b2e98dd2-8661-4c38-ae00-b7bfb535316a' User entered 'No (N)'	System	18 Apr 2021 18:07:38
	System	18 Apr 2021 18:07:38

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-18T13:07:37-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'b2e98dd2-8661-4c38-ae00-b7bfb535316a' User entered '18 Apr 2021 13:07:37'	System	18 Apr 2021 18:07:38
	System	18 Apr 2021 18:07:38

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-25T16:35:06-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c05a7dcf-6224-499f-b611-6f0a39e906ca' User entered 'No (N)'	System	25 Apr 2021 21:35:17

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-25T16:35:10-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c05a7dcf-6224-499f-b611-6f0a39e906ca' User entered 'No (N)'	System	25 Apr 2021 21:35:17

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-04-25T16:35:14-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: 'c05a7dcf-6224-499f-b611-6f0a39e906ca' User entered '25 Apr 2021 16:35:14'	System	25 Apr 2021 21:35:17
	System	25 Apr 2021 21:35:17

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-05-02T12:06:56-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '69917664-3b12-47a4-8b82-9303a0e3288e'	System	02 May 2021 17:09:28
User entered 'No (N)'	System	02 May 2021 17:09:28

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-05-02T12:06:59-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '69917664-3b12-47a4-8b82-9303a0e3288e'	System	02 May 2021 17:09:28
User entered 'No (N)'	System	02 May 2021 17:09:28

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-05-02T12:07:02-05:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '69917664-3b12-47a4-8b82-9303a0e3288e'	System	02 May 2021 17:09:28
User entered '02 May 2021 12:07:02'	System	02 May 2021 17:09:28

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:14:11

US3912114

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:14:11
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:14:11

US3912114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:16:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:29:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-28T07:22:07-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7a661e0c-ef2a-4fee-87a1-d6f3953d18cd' User entered 'No (N)'	System	28 Feb 2021 13:22:30
	System	28 Feb 2021 13:22:30

US3912114

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:16:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:29:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9155B8A3-F9D3-4165-B6F8-B5102B88E2FC)', Time: '2021-02-28T07:22:27-06:00', User OID: 'PatientReportedOutcome (US3912114)', ODM File OID: '7a661e0c-ef2a-4fee-87a1-d6f3953d18cd' User entered '28 Feb 2021 13:22:27'	System	28 Feb 2021 13:22:30
	System	28 Feb 2021 13:22:30

US3912114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	08 Dec 2020 23:06:47

US3912114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '24 Nov 2020'	(b) (4)	08 Dec 2020 23:06:47
	Monique Gawlik (b) (4)	

US3912114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	08 Dec 2020 23:06:47

US3912114

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) Monique Gawlik (b) (4)	08 Dec 2020 23:06:47

US3912114

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	08 Dec 2020 23:07:00

US3912114

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:23
User entered '1'	System	08 Dec 2020 23:07:00

US3912114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 23:17:02

US3912114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '30 Dec 2020'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 23:17:02

US3912114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 23:17:02

US3912114

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 23:17:02

US3912114

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	30 Dec 2020 23:17:08

US3912114

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered '1'	System	30 Dec 2020 23:17:08

US3912114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 15:23:58

US3912114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '2 Feb 2021'	Sandra Clancy (b) (4)	09 Feb 2021 15:23:58

US3912114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4)	09 Feb 2021 15:23:58

US3912114

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 15:23:58

US3912114

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 15:24:09

US3912114

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered '1'	System	09 Feb 2021 15:24:09

US3912114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	Mia Rountree (b) (4)	05 Mar 2021 15:45:29

US3912114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1 Mar 2021'	Mia Rountree (b) (4)	05 Mar 2021 15:45:29

US3912114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	05 Mar 2021 15:45:29

US3912114

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	05 Mar 2021 15:45:29

US3912114

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	Mia Rountree (b) (4)	05 Mar 2021 15:45:37

US3912114

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered '1'	System	05 Mar 2021 15:45:37

US3912114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:29

US3912114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	30 Mar 2021 21:19:29

US3912114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered 'Clinic (Clinic)'	Sandra Clancy (b) (4)	30 Mar 2021 21:19:29

US3912114

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered 'VISIT4'	System	30 Mar 2021 21:19:29

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	Sandra Clancy (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	Sandra Clancy (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered empty.	System	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered empty.	System	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered empty.	System	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered empty.	System	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered empty.	System	30 Mar 2021 21:19:49

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15

US3912114

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15

US3912114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:20:00

US3912114

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered empty.	Sandra Clancy (b) (4)	30 Mar 2021 21:20:00

US3912114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:20:30

US3912114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered '30 Mar 2021'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:20:30

US3912114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered '13:37'	Sandra Clancy (b) (4)	30 Mar 2021 21:20:30

US3912114

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered '30 Mar 2021 13:37'	System	30 Mar 2021 21:20:30

US3912114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:51:53
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 21:20:48

US3912114

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:15
User entered '1'	System	30 Mar 2021 21:20:48

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:05
User entered '30 Oct 2020'	Amy Collins (b) (4) (b) (4)	03 Nov 2020 15:50:03

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:05
User entered '11:27'	Amy Collins (b) (4) (b) (4)	03 Nov 2020 15:50:03

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:26
User entered '30 Oct 2020 11:27'	System	03 Nov 2020 15:50:03

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:05
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Amy Collins (b) (4) (b) (4)	03 Nov 2020 15:50:03

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:26
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:05
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	03 Nov 2020 15:50:03

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 1 (Day 1)'	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '16 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:54:57

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 2 (Day 2)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '17 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 3 (Day 3)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '18 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 4 (Day 4)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '19 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 5 (Day 5)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '20 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 6 (Day 6)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '21 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 7 (Day 7)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '22 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Nov 2020 23:57:00
User entered '0'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 8 (Day 8)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '23 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Nov 2020 23:57:00
User entered '0'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 9 (Day 9)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '24 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Nov 2020 23:57:00
User entered '0'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 10 (Day 10)'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '25 Oct 2020'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4)	09 Nov 2020 23:57:00
User entered '0'	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	09 Nov 2020 23:56:41

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 11 (Day 11)'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '26 Oct 2020'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 12 (Day 12)'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '27 Oct 2020'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 13 (Day 13)'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '28 Oct 2020'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 14 (Day 14)'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '29 Oct 2020'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered empty.	System	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 15 (Day 15)'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered '0'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered '98'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered '%'	System	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered '36.5' C	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:36
User entered 'Mild (Mild)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:45
User entered 'None (None)'	Mia Rountree (b) (4) (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 16 (Day 16)' reason for change:	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
Data Entry Error	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
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	10 Nov 2020 00:03:44
User entered '31 Oct 2020' reason for change: Data Entry Error	System	10 Nov 2020 00:03:44
User opened query 'Data is required. Please complete.' (Site from System).	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	(b) (4)	
	System	10 Nov 2020 00:00:16
	Mia Rountree (b) (4)	10 Nov 2020 00:00:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '0'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '99' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered '%'	System	10 Nov 2020 00:03:44
User entered empty.	System	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '36.4' C reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (16)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 17 (Day 17)' reason for change:	(b) (4)	
Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	10 Nov 2020 00:00:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
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	10 Nov 2020 00:03:44
User entered '01 Nov 2020' reason for change: Data Entry Error	System	10 Nov 2020 00:03:44
User opened query 'Data is required. Please complete.' (Site from System).	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	(b) (4)	
	System	10 Nov 2020 00:00:16
	Mia Rountree (b) (4)	10 Nov 2020 00:00:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '0'	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '97' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered '%'	System	10 Nov 2020 00:03:44
User entered empty.	System	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '36.4' C reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (17)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)' reason for change: Data Entry Error	Mia Rountree (b) (4)	10 Nov 2020 00:03:44
User entered empty.	Mia Rountree (b) (4)	10 Nov 2020 00:00:16

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Day 18 (Day 18)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '02 Nov 2020'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '0'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '99'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User entered '%'	System	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '36.4' C	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

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Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: Symptom Log (18)

Generated On: 10 Jun 2021 10:16:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:34
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'None (None)'	Mia Rountree (b) (4)	10 Nov 2020 00:04:42

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[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 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[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 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered empty.	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[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 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered empty.	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:55:58
User entered empty.	Mia Rountree (b) (4) (b) (4)	09 Nov 2020 23:48:21

US3912114

Folder: Covid-19 Assessment 30 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:16:35

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:54:40
User entered '0'	System	09 Nov 2020 23:48:21

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 3 (Day 3)'	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:25:32

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:23
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:54:14
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:25:32

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:23
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:54:14
User entered '1 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:25:32

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 5 (Day 5)'	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:26:04

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:21
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:54:17
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:26:04

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:54:21
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:54:17
User entered '3 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:26:04

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:16:35

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:16:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:33

US3912114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 18:26:52

US3912114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:27
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 18:26:52

US3912114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Oct 2020 18:26:52

US3912114

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User entered 'SICKD1'	System	30 Oct 2020 18:26:52

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered '11:38'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User entered '30 Oct 2020 11:38'	System	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered '60.0' in	(b) (4), (b) (6)	30 Oct 2020 18:27:38
DataPoint set to visible.	System	30 Oct 2020 18:26:52

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	30 Oct 2020 18:27:38
DataPoint set to visible.	System	30 Oct 2020 18:26:52

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered '36.5' C	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:59
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:48
User entered '68'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User entered 'bpm'	System	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:45
User entered '16'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User entered 'breaths/min'	System	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:50
Query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:58:07
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP $\leq$ 89 or $\geq$ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:56:57
User entered '184'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User entered 'mmHg'	System	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:52:52
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:58:10
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:56:58
User entered '100'	(b) (4), (b) (6)	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User entered 'mmHg'	System	30 Oct 2020 18:27:38

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56

US3912114

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56

US3912114

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 18:27:50

US3912114

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:18
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 18:27:50

US3912114

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:16:35

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 18:27:57

US3912114

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 10:16:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:40:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 21:53:26
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 01NOV2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 04:25:27
Query 'Per GCL Lab Recon: Saliva: Sample dated 01NOV2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' answered with 'saliva log completed' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Nov 2020 20:26:33
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 01NOV2020 for Day 3 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:31:59
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 18:27:57

US3912114

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:31:47
	(b) (4)	

US3912114

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:31:47
	(b) (4)	

US3912114

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Clinic (Clinic)'	Sandra Clancy (b) (4)	12 Feb 2021 23:31:47
	(b) (4)	

US3912114

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'UNBLND_DECIDE'	System	12 Feb 2021 23:31:47

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	12 Feb 2021 23:32:40
	(b) (4)	
User entered '12 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:11:32
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:40:44

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:11:32
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:40:44

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	12 Feb 2021 23:32:40
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	12 Feb 2021 23:32:40
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	12 Feb 2021 23:32:15
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Not Administered (NA)'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:32:15
	(b) (4)	

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered empty.	System	12 Feb 2021 23:32:15

US3912114

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '1'	System	12 Feb 2021 23:32:15

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered empty.	System	12 Feb 2021 23:33:55
DataPoint set to visible.	System	12 Feb 2021 23:32:15

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered empty.	System	12 Feb 2021 23:33:55
DataPoint set to visible.	System	12 Feb 2021 23:32:15

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '14:22'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '11 Feb 2021 14:22'	System	12 Feb 2021 23:33:55

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '97.4' F	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Oral (Oral)'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '70'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'bpm'	System	12 Feb 2021 23:33:55

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '12'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'breaths/min'	System	12 Feb 2021 23:33:55

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '149'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'mmHg'	System	12 Feb 2021 23:33:55

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '84'	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'mmHg'	System	12 Feb 2021 23:33:55

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered missing code ND - Not Done.	Sandra Clancy (b) (4)	12 Feb 2021 23:33:55
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered empty.	System	12 Feb 2021 23:33:55
DataPoint set to visible.	System	12 Feb 2021 23:32:15

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '15:45'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '11 Feb 2021 15:45'	System	12 Feb 2021 23:40:05

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '97.7' F	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Oral (Oral)'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '70'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'bpm'	System	12 Feb 2021 23:40:05

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '14'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'breaths/min'	System	12 Feb 2021 23:40:05

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '133'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'mmHg'	System	12 Feb 2021 23:40:05

US3912114

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '81'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:05
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'mmHg'	System	12 Feb 2021 23:40:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:25
	(b) (4)	

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:25
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:51
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	12 Feb 2021 23:40:51
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	12 Feb 2021 23:40:51
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'mRNA-1273'	System	12 Feb 2021 23:40:51
DataPoint set to visible.	System	12 Feb 2021 23:32:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:51
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '15:08'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:51
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '11 Feb 2021 15:08'	System	12 Feb 2021 23:40:51

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sandra Clancy (b) (4)	12 Feb 2021 23:40:51
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'ONCE'	System	12 Feb 2021 23:40:51

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 23:40:51

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:11
	(b) (4)	

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:11
	(b) (4)	

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '14:02'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:11
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '11 Feb 2021 14:02'	System	12 Feb 2021 23:41:11

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:25
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '11 Feb 2021'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:25
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '14:06'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:25
	(b) (4)	

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '11 Feb 2021 14:06'	System	12 Feb 2021 23:41:25

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	12 Feb 2021 23:41:29
	(b) (4)	

US3912114

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:08:54
User entered '1'	System	12 Feb 2021 23:41:29

US3912114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:32:36

US3912114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 13:14:21
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is correct ' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 17:32:50
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Feb 2021 17:32:36
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 17:32:36

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:32:36

US3912114

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:32:36

US3912114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 17:33:01

US3912114

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User entered '1'	System	23 Feb 2021 17:33:01

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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:20
User entered '1'	System	23 Feb 2021 17:33:01
DataPoint set to visible.	System	23 Feb 2021 17:33:01

US3912114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:30:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:30:04
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:03:34

US3912114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:30:04
User entered '12 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:30:04
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:34

US3912114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:30:04
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:30:04
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:34

US3912114

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered 'OLD29'	System	17 Mar 2021 14:03:34

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered '12 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered '11:30' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered '12 Mar 2021 11:30'	System	19 Mar 2021 17:31:52
User entered empty.	System	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered '98.0' F reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	19 Mar 2021 17:32:11
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	19 Mar 2021 17:32:11
User entered '81' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:32:11
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Signature has been broken.	System	19 Mar 2021 17:31:52
User entered '16' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	(b) (4)	
User entered empty.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
	(b) (4)	
	Mia Rountree (b) (4)	17 Mar 2021 14:03:43
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered 'bpm'	System	19 Mar 2021 17:31:52
User entered empty.	System	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	19 Mar 2021 17:32:11
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	19 Mar 2021 17:32:11
User entered '16' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:32:11
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	19 Mar 2021 17:31:52
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered '81' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered empty.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
	(b) (4)	17 Mar 2021 14:03:43
	Mia Rountree (b) (4)	
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered 'breaths/min'	System	19 Mar 2021 17:31:52
User entered empty.	System	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered '128' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered 'mmHg'	System	19 Mar 2021 17:31:52
User entered empty.	System	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User entered '84' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:31:52
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered 'mmHg'	System	19 Mar 2021 17:31:52
User entered empty.	System	17 Mar 2021 14:03:43

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04

US3912114

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04

US3912114

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:33:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:33:05
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:03:49

US3912114

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:33:05
User entered '12 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:33:05
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:49

US3912114

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:33:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:33:29
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:03:54

US3912114

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User closed query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 12 MAR 2021 is recorded under the OL-D29 visit in EDC, however the same is reported under in OL-D57(OL-3) visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 15:26:35
Query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 12 MAR 2021 is recorded under the OL-D29 visit in EDC, however the same is reported under in OL-D57(OL-3) visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you' answered with 'sample should be labeled OL-D29 - data here is correct' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	06 Apr 2021 15:41:15
User opened query 'Per GCL Lab Recon:LB4 Immuno: Sample dated 12 MAR 2021 is recorded under the OL-D29 visit in EDC, however the same is reported under in OL-D57(OL-3) visit in PPD GCL. Please reconcile and confirm the correct Visit and update in EDC or Preclarus as necessary by sending a DCF if applicable. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:09:53
User closed query 'Per Lab Recon:OL-D29: Immuno: Sample dated 12 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.	(b) (4), (b) (6)	05 Apr 2021 13:08:16

' (Site from DM).

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per Lab Recon:OL-D29: Immuno: Sample dated 12 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you. ' answered with 'confirmed that sample has been collected & shipped. FedEx tracking #: />1002286101810004107000972765285439. date of shipment = 23-mar-21' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	01 Apr 2021 21:49:52
User opened query 'Per Lab Recon:OL-D29: Immuno: Sample dated 12 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.	(b) (4), (b) (6)	26 Mar 2021 11:48:08
' (Site from DM).		
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	19 Mar 2021 17:33:29
User entered '12 Mar 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	19 Mar 2021 17:33:29
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4) (b) (4)	17 Mar 2021 14:03:54

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Mar 2021 21:29:16
Signature has been broken.	Sandra Clancy (b) (4)	19 Mar 2021 17:33:29
User entered '11:53' reason for change: Data Entry Error	Sandra Clancy (b) (4)	19 Mar 2021 17:33:29
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:03:54

US3912114

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:49:04
User entered '12 Mar 2021 11:53'	System	19 Mar 2021 17:33:29
User entered empty.	System	17 Mar 2021 14:03:54

US3912114

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:51:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Sep 2020 18:11:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per CDM: Please note that HYPERTENSION is already reported on the MH eCRF, the AE should be recorded only if it is worsening of the pre-existing condition as per protocol section 8.3.1. If related to the MH and worsening, please update the AE TERM to reflect "worsening". Please review and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:32:04
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:33:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:33:59
Data point term sent to Coder	System	23 Nov 2020 15:33:23
Query 'Per CDM: Please note that HYPERTENSION is already reported on the MH eCRF, the AE should be recorded only if it is worsening of the pre-existing condition as per protocol section 8.3.1. If related to the MH and worsening, please update the AE TERM to reflect "worsening". Please review and update accordingly or provide clarification. Thank you.'	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:32:57
answered with 'Data updated' (Site from DM).		
Coding entries removed.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:32:40
User entered 'Worsening of HYPERTENSION' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:32:40
User opened query 'Per CDM: Please note that HYPERTENSION is already reported on the MH eCRF, the AE should be recorded only if it is worsening of the pre-existing condition as per protocol section 8.3.1. If related to the MH and worsening, please update the AE TERM to reflect "worsening". Please review and update accordingly or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:52:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
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 Sep 2020 18:14:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 18:14:34
Data point term sent to Coder	System	06 Sep 2020 18:13:49
User entered 'hypertension'	(b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '17:06'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User entered '04 Sep 2020 17:06'	System	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:21:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:21:40
User entered empty.	(b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per CDM: Per page 36 of CCGs Version 2.0, If Adverse Event ended within 24 hours of dosing time, then the field must be completed. Enter the End time of the AE in 24-hour clock format (HH:MM). Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 09:41:46
Query 'Per CDM: Per page 36 of CCGs Version 2.0, If Adverse Event ended within 24 hours of dosing time, then the field must be completed. Enter the End time of the AE in 24-hour clock format (HH:MM). Thank you.' answered with 'per source subject reported a return to 'normal' blood pressure the following morning (05sept2020). A time of resolution is unknown.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Nov 2020 14:34:03
User opened query 'Per CDM: Per page 36 of CCGs Version 2.0, If Adverse Event ended within 24 hours of dosing time, then the field must be completed. Enter the End time of the AE in 24-hour clock format (HH:MM). Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:02:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 12:52:07
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 15:21:53
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 15:21:40
User entered empty.	(b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User entered empty.	System	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:32:18
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:33:05
' answered with 'Data updated ' (Site from DM). User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:32:40
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:32:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of [HYPERTENSION]. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 09:51:14
Query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of [HYPERTENSION]. Please clarify and update as appropriate.' answered with 'Hypertension medication taken prior to AE for pre-existing hypertension condition' (Site from DM).	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:24:08
User opened query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of [HYPERTENSION]. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 07:39:26
User entered '1'	(b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:21:40
User closed query 'Per CDM: Outcome is missing. Please consider to select appropriate outcome from the available option in this field. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 06:28:18
Query 'Per CDM: Outcome is missing. Please consider to select appropriate outcome from the available option in this field. Thank you' answered with 'ongoing at this time' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:49:58
User opened query 'Per CDM: Outcome is missing. Please consider to select appropriate outcome from the available option in this field. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:50:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 07:46:05
Query 'Data is required. Please complete.' answered with 'ongoing at this time' (Site from System).	(b) (4), (b) (6)	06 Sep 2020 18:13:30
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 18:12:54
User entered empty.	(b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

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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)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User entered '0'	System	06 Sep 2020 18:12:54

US3912114

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18
User entered '0'	System	06 Sep 2020 18:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pruritus, LLT: Injection site itching - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 16:15:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 16:15:44
Data point term sent to Coder	System	26 Sep 2020 15:21:30
User entered 'injection site reaction Left deltoid (itching)'	(b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	16 Oct 2020 23:49:48
User entered empty; reason for change Per Query Resolution	Monique Gawlik (b) (4)	16 Oct 2020 23:49:48
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Oct 2020 23:48:26
User entered '07:00' reason for change: Data Entry Error	Monique Gawlik (b) (4)	16 Oct 2020 23:48:26
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Sep 2020 15:21:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:21:21
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	26 Sep 2020 15:20:50
User entered '07:00'	(b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User entered empty.	System	16 Oct 2020 23:49:48
User entered '13 Sep 2020 07:00'	System	16 Oct 2020 23:48:26
User entered empty.	System	26 Sep 2020 15:21:21
User entered '13 Sep 2020 07:00'	System	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:22:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:22:21
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User entered empty.	System	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

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Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

US3912114

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Related (RELATED)' reason for change: New Information	(b) (4) Monique Gawlik (b) (4)	16 Oct 2020 23:47:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per CDM: Other action taken is checked as 'Concomitant Medication'. However, please consider updating the indication in Concomitant medication page to match the Adverse event in AE page if appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:20:22
Query 'Per CDM: Other action taken is checked as 'Concomitant Medication'. However, please consider updating the indication in Concomitant medication page to match the Adverse event in AE page if appropriate. Thank you.' answered with 'Data corrected in Concomitant medication page to match the Adverse even ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:30:33
User opened query 'Per CDM: Other action taken is checked as 'Concomitant Medication'. However, please consider updating the indication in Concomitant medication page to match the Adverse event in AE page if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 02:29:52
User entered '1'	(b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:22:21
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:21:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 15:21:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:21:21
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:20:50
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User entered '0'	System	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24
User entered '0'	System	26 Sep 2020 15:20:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Re-Query: Response noted. However, as the condition is ongoing in medical history kindly consider updating AE term to worsening of ongoing medical condition. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 11:59:47
Query 'Per DM CLR: Re-Query: Response noted. However, as the condition is ongoing in medical history kindly consider updating AE term to worsening of ongoing medical condition. Please review and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 18:58:20
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:57:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 18:57:57
Data point term sent to Coder	System	12 Jan 2021 18:48:32
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 18:47:48
User entered 'HYPERTENSION, worsening' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 18:47:48
User opened query 'Per DM CLR: Re-Query: Response noted. However, as the condition is ongoing in medical history kindly consider updating AE term to worsening of ongoing medical condition. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 08:59:25
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 08:59:25

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'subject was recently diagnosed with hypertension and per subject, she may have not been taking her medications as prescribed. In addition, the subject reports that she gets hypertensive at any dr. office (white coat syndrome).' (Site from DM).	Sandra Clancy (b) (4)	11 Jan 2021 22:00:53
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 03:17:04
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:40:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	06 Nov 2020 14:40:17
Data point term sent to Coder	System	06 Nov 2020 14:38:44
User entered 'Hypertension'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '30 Oct 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	06 Nov 2020 14:39:05
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	06 Nov 2020 14:39:05
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	06 Nov 2020 14:38:31
User entered '11:38'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User entered empty.	System	06 Nov 2020 14:39:05
User entered '30 Oct 2020 11:38'	System	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '04 Nov 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	06 Nov 2020 14:39:05
User entered empty; reason for change Data Entry Error	Mia Rountree (b) (4)	06 Nov 2020 14:39:05
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	06 Nov 2020 14:38:31
User entered '12:23'	System	06 Nov 2020 14:38:31
	Mia Rountree (b) (4)	06 Nov 2020 14:38:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User entered empty.	System	06 Nov 2020 14:39:05
User entered '04 Nov 2020 12:23'	System	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User entered '0'	System	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31
User entered '0'	System	06 Nov 2020 14:38:31

US3912114

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:31

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:35:45
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	Sandra Clancy (b) (4)	23 Feb 2021 22:21:58
' answered with 'yes she was brought in for Illness visit 30Oct2020; NS swab results of that day were negative for Covid.'	(b) (4)	
' (Site from DM).		
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4), (b) (6)	15 Feb 2021 12:55:41
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Respiratory disorder, LLT: Upper respiratory disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:36:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 18:36:33
Data point term sent to Coder	System	06 Nov 2020 14:40:50
User entered 'Mucus in posterior oropharynx'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '30 Oct 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User entered empty.	System	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
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) (4), (b) (6)	20 Jan 2021 12:00:06
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 18:45:02
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	12 Jan 2021 18:44:20
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 03:17:14
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '4 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	12 Jan 2021 18:44:20
User entered empty.	(b) (4)	
	Mia Rountree (b) (4)	06 Nov 2020 14:40:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User entered empty.	System	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	12 Jan 2021 18:44:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User entered '0'	System	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38
User entered '0'	System	06 Nov 2020 14:40:36

US3912114

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:38

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:00:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:00:17
Data point term sent to Coder	System	06 Nov 2020 14:43:53
User entered 'Right shoulder pain'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User entered empty.	System	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
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) (4), (b) (6)	12 Jan 2021 09:02:57
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 22:03:07
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 22:02:51
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 22:02:51
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 03:17:27
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	Sandra Clancy (b) (4)	11 Jan 2021 22:02:51
User entered '1 Jan 2021' reason for change: Data Entry Error	Sandra Clancy (b) (4)	11 Jan 2021 22:02:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User entered empty.	System	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:13
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:11
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:09:10
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:53
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:51
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:49
User entered '1'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:48
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	11 Jan 2021 22:02:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Sandra Clancy (b) (4)	11 Jan 2021 22:02:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:08:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mia Rountree (b) (4)	06 Nov 2020 14:43:04
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:45
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:08:43
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User entered '0'	System	06 Nov 2020 14:43:04

US3912114

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10
User entered '1'	System	06 Nov 2020 14:43:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:11:10

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:09:15
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:37:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:50:02
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:05
User entered	System	12 Nov 2020 13:10:59
'USA-US211-2020-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 13:10:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:30
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: This AE was noted as a result of FALL. However, there is no recorded AE of FALL that would support this AE. Please update to record the corresponding AE of Fall as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 09:46:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Humerus fracture, LLT: Humerus fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 14:32:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 14:32:57
Data point term sent to Coder	System	09 Feb 2021 14:32:02
Query 'Per DM CLR: This AE was noted as a result of FALL. However, there is no recorded AE of FALL that would support this AE. Please update to record the corresponding AE of Fall as appropriate. Otherwise, clarify.' answered with 'clarified' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 14:31:38
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 14:31:26
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 14:31:26
User entered 'BROKEN RIGHT HUMERUS' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 14:31:26
User opened query 'Per DM CLR: This AE was noted as a result of FALL. However, there is no recorded AE of FALL that would support this AE. Please update to record the corresponding AE of Fall as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 15:07:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:57:36
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Humerus fracture, LLT: Humerus fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 06:04:15

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 06:04:15
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	System	20 Nov 2020 17:11:40
	Mia Rountree (b) (4)	20 Nov 2020 17:11:32
	(b) (4)	
Coding entries removed.	Mia Rountree (b) (4)	20 Nov 2020 17:11:32
	(b) (4)	
User entered 'BROKEN RIGHT HUMERUS (Related to fall)' reason for change: Data Entry Error	Mia Rountree (b) (4)	20 Nov 2020 17:11:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Humerus fracture, LLT: Humerus fracture - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:54:18
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 14:54:18
Data point term sent to Coder	(b) (4)	
User entered 'Broken right humerus'	System	06 Nov 2020 14:44:54
	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:05
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:07
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:08
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:10
User entered '30 Oct 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 14:44:28

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:50:13
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 23:51:59
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:51:59
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	11 Nov 2020 23:51:19
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:16:24
User closed query 'Per AE Form #6, end date of broken right humerus was 10Nov2020. Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:16:21
Query 'Per AE Form #6, end date of broken right humerus was 10Nov2020. Please clarify or correct. Thank you!' answered with 'Data corrected' (Site from CRA).	Mia Rountree (b) (4)	20 Nov 2020 16:47:15
	(b) (4)	
DataPoint Un-verified.	Mia Rountree (b) (4)	20 Nov 2020 16:45:47
	(b) (4)	
User entered '10 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4)	20 Nov 2020 16:45:47
	(b) (4)	
User opened query 'Per AE Form #6, end date of broken right humerus was 10Nov2020. Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:50:54
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:47:12
User entered '11 Nov 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	11 Nov 2020 23:51:19
	(b) (4)	
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:47:13
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 14:44:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:47:15
User entered 'Grade 4 (Grade 4)'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:15
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 11:44:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4)	11 Nov 2020 23:49:10
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Data is correct ' (Site from System).	(b) (4)	
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	Mia Rountree (b) (4)	06 Nov 2020 14:44:49
	(b) (4)	
User entered 'No (N)'	System	06 Nov 2020 14:44:28
	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:17
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:19
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:50:21
User entered '1' reason for change: New Information	Tina Rountree (b) (4)	11 Nov 2020 23:49:10
	(b) (4)	
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:49:23
User entered '10 Nov 2020' reason for change: New Information	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:49:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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Folder: Adverse Events

Form: Adverse Events (6)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:49:25
User entered '11 Nov 2020' reason for change: New Information	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:49:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:49:26
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:49:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:51:07
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:08
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:10
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:49:28
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:49:30
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:02:31
User closed query 'Per eCRF Completion Guidelines v2.0, Page 38: "Not Applicable: If adverse event started AFTER last dose." Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 21:14:19
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 21:14:16
Query 'Per eCRF Completion Guidelines v2.0, Page 38: "Not Applicable: If adverse event started AFTER last dose." Please clarify or correct. Thank you!' answered with 'confirmed event occurred after last dose.' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:13:58
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'corrected' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:13:39
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:12:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:12:21
User opened query 'Per eCRF Completion Guidelines v2.0, Page 38: "Not Applicable: If adverse event started AFTER last dose." Please clarify or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 18:34:25
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:32:02
User entered 'None (NONE)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	30 Nov 2020 16:16:56
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	30 Nov 2020 16:16:32
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	30 Nov 2020 16:16:32

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 14:50:32
	(b) (4), (b) (6)	18 Nov 2020 17:49:32
User entered 'None (NONE)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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None

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 19:37:51
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	11 Jan 2021 22:04:36
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4)	11 Jan 2021 22:04:36
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	11 Jan 2021 22:04:03
DataPoint Un-verified.	Sandra Clancy (b) (4)	11 Jan 2021 22:04:03
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4)	11 Jan 2021 22:04:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:49:38
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:41
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #20 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:38:06
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #20 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 22:24:05
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 22:23:54
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Feb 2021 22:23:54
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConMed #20 recorded that machth this AE during this timeframe. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:25:20
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 19:37:52
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 11:00:43
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 22:04:13
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 22:04:03
User entered '0' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 22:04:03

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 03:17:43
	(b) (4), (b) (6)	18 Nov 2020 17:49:36
User entered '1'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:49:35
User entered '1' reason for change: New Information	Tina Rountree (b) (4)	11 Nov 2020 23:49:10
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:44:28

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:49:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:51:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:44:28

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:49:39
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:44:28
	(b) (4)	

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Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Query 'PV Query: Please remove event Fall from event tab. Per FU received 11Jan2021 a single event of broken right humerus (related to fall) was reported by the Investigator.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 14:46:08
User opened query 'PV Query: Please remove event Fall from event tab. Per FU received 11Jan2021 a single event of broken right humerus (related to fall) was reported by the Investigator.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 14:45:43
User closed query 'PV Query: Please consider reporting Fall as an additional AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:59:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:59:46
Query 'PV Query: Please consider reporting Fall as an additional AE/SAE.' answered with 'subject tripped across debris on the floor; tripping does not meet AE definitions.' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 18:25:53
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' answered with 'subject had negative Covid test on 09Nov2020 at the hospital.' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 18:11:38
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 12:02:35
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'accidental' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:15:59
User opened query 'PV Query: Please consider reporting Fall as an additional AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:51:03
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:50:51

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Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:47:24
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)	25 Nov 2020 12:41:39
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' answered with 'SARSCOV2 nasopharyngeal swab performed 09Nov2020, with negative results.' (Site from Safety).	Sandra Clancy (b) (4)	24 Nov 2020 16:11:36
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:06:37
User closed query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:06:23
User closed query 'PV Query: Please provide the etiology of the broken right humerus (I.e fall, other injury).' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:06:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' answered with 'No relevant or diagnostic test results received' (Site from Safety).	Mia Rountree (b) (4)	20 Nov 2020 17:11:21
Query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event.' answered with 'Subjects last does was 04 Sep 2020' (Site from Safety).	Mia Rountree (b) (4)	20 Nov 2020 17:10:17
Query 'PV Query: Please provide the etiology of the broken right humerus (I.e fall, other injury).' answered with 'Etiology added in AE title' (Site from Safety).	Mia Rountree (b) (4)	20 Nov 2020 17:09:33

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If none, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:20:51
User opened query 'PV Query: Please provide the date the subject's last dose of study medication was taken prior to the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:20:40
User opened query 'PV Query: Please provide the etiology of the broken right humerus (I.e fall, other injury).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:20:29
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)	20 Nov 2020 16:20:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:49:41
User entered 'Subject had surgery to repair fracture. Subject was hospitalized overnight following surgery. She is now at home and doing well.' reason for change: Data Entry Error	Tina Rountree (b) (4)	11 Nov 2020 23:49:10
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:44:28

US3912114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 23:49:10
User entered '0'	System	06 Nov 2020 14:44:28

US3912114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 14:44:28

US3912114

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 23:49:10

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Hordeolum, LLT: Stye - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Mar 2021 07:12:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:12:54
Data point term sent to Coder	System	17 Mar 2021 13:57:18
User entered 'Stye (bilateral eyes)'	Mia Rountree (b) (4) (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Yes (Y)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '15 Feb 2021'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User entered empty.	System	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '07 Mar 2021'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User entered empty.	System	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '1'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User entered '0'	System	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54
User entered '1'	System	17 Mar 2021 13:57:13

US3912114

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:54

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:28:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:28:16
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	06 Apr 2021 21:23:58
Data point term sent to Coder	System	06 Apr 2021 18:05:38
User entered 'seasonal allergy- active'	(b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered empty.	System	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '31 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered empty.	System	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '1'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 21:23:58
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered '0'	System	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42
User entered '1'	System	06 Apr 2021 18:04:38

US3912114

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:09:42

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:16:35

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:52:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 15:22:12

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Sep 2020 12:54:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:54:43
Data point term sent to Coder	System	26 Sep 2020 15:23:34
User entered 'levothroxin'	(b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'hypothyroidism'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0.05'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 15:22:52

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Sep 2020 15:26:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:26:40
Data point term sent to Coder	System	26 Sep 2020 15:25:36
User entered 'crestor'	(b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'hypercholesterolemia'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '20'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'un UNK 2018'	(b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:24:55

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Sep 2020 15:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:27:40
Data point term sent to Coder	System	26 Sep 2020 15:26:37
User entered 'lisinopril'	(b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '10'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:25:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 15:25:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:25:45
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:25:41
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:25:41

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 15:28:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:28:40
Data point term sent to Coder	System	26 Sep 2020 15:27:38
User entered 'fish oil'	(b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:26:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 15:26:56
User entered 'supplement' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:26:56
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:26:45
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1400'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:26:45

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
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)	26 Sep 2020 15:29:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:29:41
Data point term sent to Coder	System	26 Sep 2020 15:28:38
User entered 'aspirin'	(b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please update CM indication to include the specific medical condition/diagnosis that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Coronary Artery disease prophylaxis, DVT prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 14:58:46
Query 'Per DM CLR: Please update CM indication to include the specific medical condition/diagnosis that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Coronary Artery disease prophylaxis, DVT prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' answered with 'data correct. This is taken for cardiac prophylaxis. There is not a condition or diagnosis that it is associated with.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 23:49:15
User opened query 'Per DM CLR: Please update CM indication to include the specific medical condition/diagnosis that this medication is being given to prevent (i.e.: Cardiovascular prophylaxis, Coronary Artery disease prophylaxis, DVT prophylaxis etc.). Please update CM page and ensure to reconcile with the MH page so there is a match as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:50:12
User entered 'cardiac'	(b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '81'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:27:46

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE, PRODUCTSYNONYM: OSTEO-BI-FLEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Sep 2020 13:54:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 13:54:38
Data point term sent to Coder	System	26 Sep 2020 15:29:39
Data point term sent to Coder	System	26 Sep 2020 15:28:38
User entered 'osteo bi-flex'	(b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:28:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 15:28:51
User entered 'supplement' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:28:51
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:28:34
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:28:34

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM WITH D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 15:30:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 15:30:41
Data point term sent to Coder	System	26 Sep 2020 15:29:39
User entered 'calcium with D3'	(b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '600'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:29:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 15:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:31:41
Data point term sent to Coder	System	26 Sep 2020 15:30:39
User entered 'multivitamin'	(b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:30:05

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 15:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:31:41
Data point term sent to Coder	System	26 Sep 2020 15:30:40
User entered 'vitamin D'	(b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '2000'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'un UNK 2011'	(b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:30:37

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 15:32:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:32:41
Data point term sent to Coder	System	26 Sep 2020 15:31:41
User entered 'biotin'	(b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '10,000'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:31:26

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: MINOXIDIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Sep 2020 15:33:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:33:41
Data point term sent to Coder	System	26 Sep 2020 15:32:41
User entered 'minoxidil 5%'	(b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:50:32
User entered 'No (N)'	(b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Note there is no MH condition of HAIR LOSS recorded on the MH page. Please reconcile and add HAIR LOSS to the MH page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:34:48
Query 'Per DM CLR: Note there is no MH condition of HAIR LOSS recorded on the MH page. Please reconcile and add HAIR LOSS to the MH page as appropriate. ' answered with 'This is Prophylaxis to prevent hair loss. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 23:50:20
User opened query 'Per DM CLR: Note there is no MH condition of HAIR LOSS recorded on the MH page. Please reconcile and add HAIR LOSS to the MH page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:50:38
User entered 'hair loss'	(b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'application'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:32:14

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
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.	(b) (4) Coder Import (b) (4) (b) (4)	26 Sep 2020 15:34:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:34:42
Data point term sent to Coder User entered 'ibuprofen'	System (b) (4), (b) (6)	26 Sep 2020 15:33:44 26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'body aches'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '800'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User entered empty.	System	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User entered empty.	System	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:02
User entered empty.	System	26 Sep 2020 15:33:33

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN MIGRAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:05:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 21:05:43
Data point term sent to Coder	System	09 Oct 2020 20:25:45
Coding entries removed.	Tina Rountree (b) (4)	09 Oct 2020 20:25:30
User entered 'Excedrin migraine' reason for change: Data Entry Error	Tina Rountree (b) (4)	09 Oct 2020 20:25:30
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)	26 Sep 2020 15:35:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 15:35:42
Data point term sent to Coder	System	26 Sep 2020 15:34:45
User entered 'ibuprofen'	(b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 07:30:10
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con EXCEDRIN MIGRAINE, # 16 (05Sep2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 07:30:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'confirmed that this event did not meet AE reporting criteria.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:22:50

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con EXCEDRIN MIGRAINE, # 16 (05Sep2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'log line 16 was duplicate and now inactivated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Dec 2020 21:19:51
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6) (b) (4)	01 Dec 2020 08:52:38
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con EXCEDRIN MIGRAINE, # 16 (05Sep2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	01 Dec 2020 08:52:06
User entered 'headache'	(b) (4), (b) (6) (b) (4)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '2' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 20:25:30
User entered '200'	Tina Rountree (b) (4)	26 Sep 2020 15:34:10
	(b) (4)	
	(b) (4), (b) (6)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Tina Rountree (b) (4)	09 Oct 2020 20:25:30
User entered 'mg (mg)'	(b) (4)	
	(b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 20:25:30
User entered 'as needed (PRN)'	Tina Rountree (b) (4)	26 Sep 2020 15:34:10
	(b) (4)	
	(b) (4), (b) (6)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 20:23:28
User entered '04 Sep 2020'	Tina Rountree (b) (4)	26 Sep 2020 15:34:10
	(b) (4)	
	(b) (4), (b) (6)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'PER CDM: Re-Query: In the Dairy Dose 1, Temperature Day, for the time point DAY 2, it was reported that participant took medication on DAY 2 (05-SEP-20). Kindly consider checking start date and stop date for Ibuprofen. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:07:26
Query 'PER CDM: Re-Query: In the Dairy Dose 1, Temperature Day, for the time point DAY 2, it was reported that participant took medication on DAY 2 (05-SEP-20). Kindly consider checking start date and stop date for Ibuprofen. Thank you.' answered with 'Updated' (Site from DM).	Tina Rountree (b) (4) (b) (4)	09 Oct 2020 20:23:35
User entered '05 Sep 2020' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	09 Oct 2020 20:23:28
User entered '5 Sep 2020' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	09 Oct 2020 20:23:13
User opened query 'PER CDM: Re-Query: In the Dairy Dose 1, Temperature Day, for the time point DAY 2, it was reported that participant took medication on DAY 2 (05-SEP-20). Kindly consider checking start date and stop date for Ibuprofen. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:12:35
User entered '4 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please note there is no AE that matches this CM indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:34:58
Query 'Per DM CLR: Please note there is no AE that matches this CM indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'Please see diary.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 23:54:32

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no AE that matches this CM indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:51:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User entered empty.	System	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User entered empty.	System	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:10
User entered empty.	System	26 Sep 2020 15:34:10

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:36:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:36:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:40:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:40:33
Data point term sent to Coder Coding entries removed.	System Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:29:38 06 Nov 2020 14:29:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:59:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 15:59:47
Data point term sent to Coder	System	26 Sep 2020 15:38:47
User entered 'BENADRYL 25mg' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Sep 2020 15:37:52
Data point term sent to Coder	System	26 Sep 2020 15:35:46
User entered 'benadryl'	(b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'INJECTION SITE REACTION LEFT DELTOID' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:29:04
User entered 'injection site reaction'	(b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '2'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User entered empty.	System	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User entered empty.	System	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:11
User entered empty.	System	26 Sep 2020 15:35:16

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 11:31:21
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 22:14:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 22:14:43
Data point term sent to Coder	System	11 Jan 2021 21:41:42
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' answered with 'amended' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 21:41:26
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 21:41:17
User entered 'BENADRYL, 1%' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 21:41:17
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:10:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:18:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 15:18:36
Data point term sent to Coder Coding entries removed.	System Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:29:38 06 Nov 2020 14:29:17
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:59:47
Data point term sent to Coder User entered 'benadryl'	System (b) (4), (b) (6)	26 Sep 2020 15:36:46 26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'INJECTION SITE REACTION LEFT DELTOID' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:29:17
User entered 'injection site reaction'	(b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'application'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '13 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 11:31:38
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 21:37:19
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 21:37:08
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '14 Sep 2020' reason for change: Data Entry Error	(b) (4)	11 Jan 2021 21:37:08
User entered empty.	Sandra Clancy (b) (4)	26 Sep 2020 15:36:13
	(b) (4)	
	(b) (4), (b) (6)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User entered empty.	System	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User entered empty.	System	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:23
User entered empty.	System	26 Sep 2020 15:36:13

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
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.	(b) (4) Coder Import (b) (4)	06 Nov 2020 14:50:17
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 14:50:17
Data point term sent to Coder	System	06 Nov 2020 14:49:00
User entered 'Influenza vaccine'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Yes (Y)'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Flu prevention'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0.5'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'mL (mL)'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'once (ONCE)'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '9 Oct 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '0'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '9 Oct 2020'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered 'No (N)'	Mia Rountree (b) (4)	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User entered empty.	System	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User entered empty.	System	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:32
User entered empty.	System	06 Nov 2020 14:48:40

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 14:58:17
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 14:58:17
Data point term sent to Coder	System	06 Nov 2020 14:51:03
User entered 'Motrin'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Right shoulder pain'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered '600'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'mg (mg)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'other (OTHER)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Every 8 hours'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Oral (ORAL)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:52
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:24:47
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:13:30
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:13:22
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:13:22
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:24:16
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:52
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	24 Feb 2021 21:13:22
User entered '1 Jan 2021' reason for change: Data Entry Error	(b) (4)	24 Feb 2021 21:13:22
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered empty.	Mia Rountree (b) (4)	06 Nov 2020 14:50:03
	(b) (4)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User entered empty.	System	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User entered empty.	System	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:38
User entered empty.	System	06 Nov 2020 14:50:03

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 15:14:17
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 15:14:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 14:59:18
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 14:59:18
Data point term sent to Coder	System	06 Nov 2020 14:51:02
User entered 'Oxycodone'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Right shoulder pain'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered '10'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'mg (mg)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'other (OTHER)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Every 6 hours'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Oral (ORAL)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered '30 Oct 2020'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered '0'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:52
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:24:59
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:14:21
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:14:11
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:14:11
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:24:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:52
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	(b) (4) Sandra Clancy (b) (4)	24 Feb 2021 21:14:11
User entered '1 Jan 2021' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	24 Feb 2021 21:14:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered empty.	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:40
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User entered empty.	System	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User entered empty.	System	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:43:59
User entered empty.	System	06 Nov 2020 14:50:56

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Jan 2021 23:49:32
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 Jan 2021 23:49:32
Data point term sent to Coder	System	06 Jan 2021 23:48:58
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	06 Jan 2021 23:48:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:56:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:56:37
Data point term sent to Coder	System	11 Nov 2020 23:55:14
User entered 'Norco'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:41
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	06 Jan 2021 23:48:50
User entered 'broken right humerus (related to fall)'	(b) (4)	
reason for change: Data Entry Error	Sandra Clancy (b) (4)	06 Jan 2021 23:48:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'Post operative pain'	Tina Rountree (b) (4)	11 Nov 2020 23:54:51
	(b) (4)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:23
User closed query 'Per source documentation, dose per administration is 10/325mg. Please correct or clarify. If correct, please enter 10/325 in the 'Dose per administration' line and leave 'Dose unit' as mg, per CCGs v2.0. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:46:21
Query 'Per source documentation, dose per administration is 10/325mg. Please correct or clarify. If correct, please enter 10/325 in the 'Dose per administration' line and leave 'Dose unit' as mg, per CCGs v2.0. ' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	24 Nov 2020 19:05:04
User entered '10/325' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	24 Nov 2020 19:04:56
User opened query 'Per source documentation, dose per administration is 10/325mg. Please correct or clarify. If correct, please enter 10/325 in the 'Dose per administration' line and leave 'Dose unit' as mg, per CCGs v2.0. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 19:02:22
User closed query 'Per CDM: Please remove additional data from Dose Per administration as only numerical values are expected (i.e. 10/32). "Mg" dose unit is available in the drop down of dose unit. Please update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 10:35:15
Query 'Per CDM: Please remove additional data from Dose Per administration as only numerical values are expected (i.e. 10/32). "Mg" dose unit is available in the drop down of dose unit. Please update appropriately. Thank you' answered with 'Data corrected' (Site from DM).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 21:05:41
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 21:05:31
User entered '1' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 21:05:31

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please remove additional data from Dose Per administration as only numerical values are expected (i.e. 10/32). "Mg" dose unit is available in the drop down of dose unit. Please update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:05:46
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered '1 (10/325mg)'	Tina Rountree (b) (4)	11 Nov 2020 23:54:51
	(b) (4)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:02:29
DataPoint Un-verified.	Mia Rountree (b) (4)	20 Nov 2020 21:05:31
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 21:05:31
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'tablet (TABLET)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered empty.	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered empty.	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered empty.	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:41
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	24 Feb 2021 21:16:21
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4)	24 Feb 2021 21:16:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered '10 Nov 2020'	Tina Rountree (b) (4)	11 Nov 2020 23:54:51
	(b) (4)	

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered '0'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:41
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:25:08
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:16:33
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:16:21
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 21:16:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:42:37
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:31:41
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Un-verified.	(b) (4) Sandra Clancy (b) (4)	24 Feb 2021 21:16:21
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	24 Feb 2021 21:16:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered empty.	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:10:41
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User entered empty.	System	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User entered empty.	System	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:05
User entered empty.	System	11 Nov 2020 23:54:51

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 13:59:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:59:45
Data point term sent to Coder	System	17 Mar 2021 13:59:20
User entered 'Doxycycline'	Mia Rountree (b) (4) (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Stye'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '75'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'mg (mg)'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'twice daily (BID)'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Oral (ORAL)'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '20 Feb 2021'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '06 Mar 2021'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User entered '2'	System	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User entered '1'	System	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:13
User entered '804 (804)'	System	17 Mar 2021 13:59:19

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS AND ANTIINFECTIVES IN COMBINATION, ATC: CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION, PRODUCT: DEXAMETHASONE;TOBRAMYCIN, PRODUCTSYNONYM: TOBRADEX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Mar 2021 07:08:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 07:08:33
Data point term sent to Coder	System	17 Mar 2021 14:02:25
User entered 'Tobradex (tobramycin dexamethasone 0.3% / 0.1%)'	Mia Rountree (b) (4) (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Stye'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '1'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Other (OTHER)'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Application'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'twice daily (BID)'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered empty.	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Other (OTHER)'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'Ophthalmic'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '20 Feb 2021'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '0'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered '06 Mar 2021'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User signature succeeded.	Mark Hutchens (b) (4)	18 Mar 2021 18:26:27
User entered 'No (N)'	Mia Rountree (b) (4)	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User entered '2'	System	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User entered '1'	System	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:44:18
User entered '804 (804)'	System	17 Mar 2021 14:02:25

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:16:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:51:32
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:55:03

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:11:28
User entered '10 Nov 2020'	Tina Rountree (b) (4)	11 Nov 2020 23:55:39
	(b) (4)	

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:11:28
User entered 'Open reduction internal fixation right humerus'	Tina Rountree (b) (4) (b) (4)	11 Nov 2020 23:55:39

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:11:28
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4)	11 Nov 2020 23:55:39
	(b) (4)	

US3912114

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:16:35

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:11:28
User entered empty.	Tina Rountree (b) (4)	11 Nov 2020 23:55:39
	(b) (4)	

US3912114

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:16:35

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:56:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '2 Oct 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	13 Jan 2021 23:21:55

US3912114

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:16:35

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:56:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	13 Jan 2021 23:21:55

US3912114

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:16:35

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:56:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User closed query 'Per CDM:If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify is mentioned as 'SUBJECT WAS FOUND TO HAVE NOT MET INCLUSION #7' however Did the participant meet all eligibility criteria? is marked as 'Yes'. Please reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 10:34:58
Query 'Per CDM:If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify is mentioned as 'SUBJECT WAS FOUND TO HAVE NOT MET INCLUSION #7' however Did the participant meet all eligibility criteria? is marked as 'Yes'. Please reconcile the data and update as appropriate. Thank you.' answered with 'due to the numerous queries on this issue, no additional changes to be made at this time.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 14:42:07
User opened query 'Per CDM:If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify is mentioned as 'SUBJECT WAS FOUND TO HAVE NOT MET INCLUSION #7' however Did the participant meet all eligibility criteria? is marked as 'Yes'. Please reconcile the data and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:44:40
User entered 'subject was found to have not met inclusion #7'	Sandra Clancy (b) (4) (b) (4)	13 Jan 2021 23:21:55

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered '12/Nov/2020 08:11'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:03:49
User entered '23/Nov/2020 15:07'	System	23 Nov 2020 20:07:12

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:03:49
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 20:07:12

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:36:11
User entered '01/Dec/2020 18:26'	System	01 Dec 2020 18:26:45

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:36:11
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 18:26:45

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered	System	12 Nov 2020 13:10:59
'USA-US211-2020-MRNA-1273-P301000005'		

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:59:45
User entered '11/Dec/2020 07:02'	System	11 Dec 2020 12:02:54

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 19:57:21
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:59:45
User entered '1'	(b) (4), (b) (6)	11 Dec 2020 12:02:54

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
	(b) (4)	
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '12/Jan/2021 19:57'	(b) (4) System	12 Jan 2021 19:57:35

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:03
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:39:20
User entered '1'	(b) (4), (b) (6)	12 Jan 2021 19:57:35

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:04
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '10/Feb/2021 09:39'	(b) (4) System	10 Feb 2021 15:40:02

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:04
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 14:09:31
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:40:02

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'USA-US211-2020-MRNA-1273-P301000005'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Yes (Y)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
DataPoint Verified.	(b) (4)	18 Nov 2020 17:51:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
	(b) (4), (b) (6)	
User entered 'No (N)'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:53
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Mark'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'timothy' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Mark'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:29:54
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
Un-reviewed for Safety.	System	24 Feb 2021 14:14:28
DataPoint Un-verified.	System	24 Feb 2021 14:14:28
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered 'Hutchens'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
Un-reviewed for Safety.	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
User entered 'vachris' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Nov 2020 00:13:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 13:11:20
User entered 'Hutchens'	System	12 Nov 2020 13:10:59

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Nov 2020 00:13:10

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:26:35
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:51:55
User entered 'US'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 14:14:28
User entered '7'	System	24 Feb 2021 14:14:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:21:24
	(b) (4)	
User entered '6'	System	10 Feb 2021 15:40:02
User entered '5'	System	12 Jan 2021 19:57:35
User entered '4'	System	11 Dec 2020 12:02:54
User entered '3'	System	01 Dec 2020 18:26:45
User entered '2'	System	23 Nov 2020 20:07:12
User entered '1'	System	12 Nov 2020 13:11:29

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '24/Feb/2021 09:14'	(b) (4) System	24 Feb 2021 14:14:28

US3912114

Folder: SAE USA-US211-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:16:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:30:05
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:11
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:14:28