

US3822154 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:54:53

All time stamps listed in this document are displayed in GMT

US3822154

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:06:48

Generated On: 10 Jun 2021 09:54:53

[Participant ID](#)

US3822154

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

US3822154

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 19:59:01

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 19:59:01

Generated On: 10 Jun 2021 09:54:53

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 19:59:01

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 19:59:01

Generated On: 10 Jun 2021 09:54:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 19:59:01

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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) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	HERPES SIMPLEX
Start date (dd MMM yyyy)	UN UNK 1987
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1987
Start Year (derived)	1987
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 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) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	DECREASED TESTOSTERONE
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	CHRONIC KIDNEY DISEASE STAGE 3
Start date (dd MMM yyyy)	11 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	LABILE HYPERTENSION
Start date (dd MMM yyyy)	06 MAY 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	CHRONIC INSOMNIA
Start date (dd MMM yyyy)	14 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	MIXED HYPERLIPIDEMIA
Start date (dd MMM yyyy)	14 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	14 NOV 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

Condition	FREQUENT URINATION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 26 Mar 2021 17:44:35

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 19:59:01

Generated On: 10 Jun 2021 09:54:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:17 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:17
Height (<i>xxx.x</i>)	70 in
Weight (<i>xxx.x</i>)	214 lb
BMI (<i>xxx.x</i>)	30.77001 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 19:59:01

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 19:59:01

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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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 19:59:01

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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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 104924

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) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

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) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	11:17 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 11:17
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:21
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 AUG 2020

What was the treatment time? (00:00-23:59) 11:51 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 11:51

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) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 AUG 2020
Collection time (00:00-23:59)	11:29 (24 HR)
Collection date and time (derived)	17 AUG 2020 11:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:38	17 AUG 2020 11:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

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 09:54:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:16

PC Open Date & Time

17 AUG 2020 12:11

PC Close Date & Time

17 AUG 2020 14:41

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 94.5 °F

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

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

PC Time Stamp	17 AUG 2020 21:41
PC Open Date & Time	17 AUG 2020 15:36
PC Close Date & Time	18 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	18 AUG 2020 21:14
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 21:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 AUG 2020 22:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **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

21 AUG 2020 21:06

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **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

22 AUG 2020 22:07

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 AUG 2020 21:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 23:33

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:17

PC Open Date & Time

17 AUG 2020 12:11

PC Close Date & Time

17 AUG 2020 14:41

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 21:42

PC Open Date & Time

17 AUG 2020 15:36

PC Close Date & Time

18 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

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

18 AUG 2020 21:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

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

19 AUG 2020 21:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 22:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

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

21 AUG 2020 21:06

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

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

22 AUG 2020 22:08

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

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

23 AUG 2020 21:33

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 12:17
PC Open Date & Time	17 AUG 2020 12:11
PC Close Date & Time	17 AUG 2020 14:41

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 21:42
PC Open Date & Time	17 AUG 2020 15:36
PC Close Date & Time	18 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:16
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 21:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 22:42
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 21:07
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 22:08
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:33
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 24 AUG 2020 23:34

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 25 AUG 2020 22:04

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 AUG 2020 23:34

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 AUG 2020 22:04

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	24 AUG 2020 23:34
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 22:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3822154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 19:59:01

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:05
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3822154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 14 SEP 2020

What was the treatment time? (00:00-23:59) 13:35 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 13:35

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

US3822154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 SEP 2020
Collection time (00:00-23:59)	13:14 (24 HR)
Collection date and time (derived)	14 SEP 2020 13:14

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:23	14 SEP 2020 13:23
Nasopharyngeal Swab 2	No		

US3822154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 13:57

PC Open Date & Time

14 SEP 2020 13:55

PC Close Date & Time

14 SEP 2020 16:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

PC Time Stamp	14 SEP 2020 20:24
PC Open Date & Time	14 SEP 2020 17:20
PC Close Date & Time	15 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	15 SEP 2020 20:44
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **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

16 SEP 2020 20:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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):

PC Time Stamp

17 SEP 2020 22:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 23:25

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 13:58

PC Open Date & Time

14 SEP 2020 13:55

PC Close Date & Time

14 SEP 2020 16:25

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 20:24

PC Open Date & Time

14 SEP 2020 17:20

PC Close Date & Time

15 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

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

15 SEP 2020 20:45

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

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

16 SEP 2020 20:44

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 22:44

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

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

18 SEP 2020 23:25

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

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

19 SEP 2020 20:50

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

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

20 SEP 2020 20:14

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 13:59
PC Open Date & Time	14 SEP 2020 13:55
PC Close Date & Time	14 SEP 2020 16:25

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☒
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☒
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 20:25
PC Open Date & Time	14 SEP 2020 17:20
PC Close Date & Time	15 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:47
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:45
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 22:44
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 23:26
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 20:51
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

21 SEP 2020 23:08

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

23 SEP 2020 22:07

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 23:40

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

25 SEP 2020 21:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 23:08

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 SEP 2020 20:03

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 23:08

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 22 SEP 2020 20:03

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 23:09
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 20:03
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 23:40
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 21:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3822154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:58:48

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	12:25 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 12:25
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	12:30 (24 HR)
Collection date and time (derived)	16 OCT 2020 12:30

US3822154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 19:59:02

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 18:21:46

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 08:25:25

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 12:00:13

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 11:53:50

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 19:37:04

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 16:57:44

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 13:17:53

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 DEC 2020 14:46:08
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 DEC 2020 12:43:49
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 JAN 2021 16:17:32
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 145

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 13:31:41

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 00:03:10

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 12:01:08

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 19:55:58

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 10:01:34
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:01:54

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 17:00:41

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 07:28:51

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAR 2021 08:08:50

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAR 2021 18:03:42

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 MAR 2021 13:52:18
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 12:03:36

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 18:05:37

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 18:24:27

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 12:22:04

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 20:04:15

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 271

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 285

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 306

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 313

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 327

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 355

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 362

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 376

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 397

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 446

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 474

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 502

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 509

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 523

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 558

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 565

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 586

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 628

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 635

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 656

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 663

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 677

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 684

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 698

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 747

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 754

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 761

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 775

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

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

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

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

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

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

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 ☐

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

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

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3822154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:54:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	Yes	03 MAR 2021 07:29:30

US3822154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:12:55

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:12:55

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:06:54

Generated On: 10 Jun 2021 09:54:53

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

Visit date (dd MMM yyyy)	15 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:06:54

Generated On: 10 Jun 2021 09:54:53

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3822154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:06:54

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:06:54

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	13:21 (24 HR)
Collection date and time (derived)	15 MAR 2021 13:21

US3822154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:54

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 17:53:38

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 17:53:38

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Date of Contact	28 DEC 2020
Time of Contact	10:48
Date and Time of Contact (derived)	28 DEC 2020 10:48
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 3119

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Date of Visit	28 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
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)	

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 16:05
Height (xxx.x)	
Weight (xxx.x)	
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	119 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	110 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3822154

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3822154

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3822154

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:38:30

Generated On: 10 Jun 2021 09:54:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3822154

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Height	70 in
Weight	206.2 lb
BMI (xxx.x)	29.64848

US3822154

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Height	70 in
Weight	206.2 lb
BMI (xxx.x)	29.64848
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 14:17
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3822154

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Height	70 in
Weight	206.2 lb
BMI (xxx.x)	29.64848
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 JAN 2021
Time of assessment (00:00-23:59)	15:34 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 15:34
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3822154

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3822154

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 14:55 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 14:55

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

US3822154

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	15 JAN 2021 14:25

US3822154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	14:35
Collection Date and Time (derived)	15 JAN 2021 14:35

US3822154

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3822154

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 11:10
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 12:17
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG

US3822154

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822154

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 11:47 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 11:47

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

What was the frequency of the study treatment dosing? ONCE

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

US3822154

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822154

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3822154

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:06:50

Generated On: 10 Jun 2021 09:54:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	13:21 (24 HR)
Collection date and time (derived)	15 MAR 2021 13:21

US3822154

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:52:34

Generated On: 10 Jun 2021 09:54:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:52:34

Generated On: 10 Jun 2021 09:54:53

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	14 SEP 2020 00:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	25 SEP 2020 23:59
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 18:52:34

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Adverse Events

Form: Adverse Events (2)

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AEID

Adverse event

INJECTION SITE ARTHRALGIA
IN MULTIPLE JOINTS

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)

14 SEP 2020

Start time (00:00-23:59)

00:00 (24 HR)

AE start date and time (derived)

14 SEP 2020 00:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:52:34

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AEID	USA-US126-2021-MRNA-1273-P30 1000001
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	09 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Mar 2021 18:52:34

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THE SUBJECT PRESENTED TO
THE EMERGENCY
DEPARTMENT ON 28-DEC-2020
WITH CHEST TIGHTNESS AND
WAS FOUND TO HAVE HAD A
RECENT HEART ATTACK. HE
WAS ADMITTED AND IS STILL
INPATIENT. SAE WILL BE
UPDATED WHEN RECORDS
HAVE BEEN RECEIVED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Mar 2021 18:52:34

Generated On: 10 Jun 2021 09:54:53

AEID	
Adverse event	ASTHMATIC SYMPTOMS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (4)

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 18:52:34

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AEID	
Adverse event	MORE FREQUENT COUGHING
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 12 Mar 2021 18:52:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 00:03:29

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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Name of Medication TESTOSTERONE CYPIONATE
200MG/ML OIL

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1992	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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Name of Medication CIALIS

Prophylaxis Yes ☐
No ☒

Indication ED

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) 12 Apr 2021 00:03:29

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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Name of Medication EZOPICLONE

Prophylaxis Yes ☐
No ☒

Indication SLEEP APNEA

Dose per administration 3

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) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ALPROZALAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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Name of Medication ALFUZOSIN

Prophylaxis Yes ☐
No ☒

Indication FREQUENT URINATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 00:03:29

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Name of Medication NASOCORT

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (7)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ALLERGY INJECTIONS

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES

Dose per administration 0.50

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

If dose unit is Other, specify CC

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) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ANASTROZOLE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

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

2X/WEEK

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) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication EXCEDRIN - ACETAMINOPHEN,
ASPIRIN, AND CAFFINE

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication PREDNISONE 1%

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (12)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT - HEART HEALTH

Dose per administration 175

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) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1500-700

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

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication PROBIOTIC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☒
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication FIBER

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 0.52

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication DIGESTIVE ENZYMES

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 (17)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication GINKO BILBOA

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 24

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 (18)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication GARLIC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 4000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication CERATINE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 3

Dose unit mg ☐
ug ☐
mL ☐
g ☒
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication VITAMIN K-2 MK7

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 100

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication VITAMIN D-3

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 (24)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication JUBLIA

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration UNK

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☒
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication HSV

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1987	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication TDAP

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration UNK

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 (27)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 MAY 2014
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAY 2014
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication INFLUENZA

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration UNK

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 (28)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ZOSTER

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration UNK

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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US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES, HEADACHE

Dose per administration 220

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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US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HEART ATTACK

Dose per administration 6.25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ELLIQUUS

Prophylaxis Yes ☐
No ☒

Indication HEART ATTACK

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication HEART ATTACK

Dose per administration 200

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify 2 TABLETS OF 200MG ONCW A
DAY FOR 4 WEEKS

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 (33)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication MORE FREQUENT COUGHING
AND ASTHMATIC SYMPTOMS

Dose per administration 90

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☒
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 12 Apr 2021 00:03:29

Generated On: 10 Jun 2021 09:54:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 21:06:49

Generated On: 10 Jun 2021 09:54:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 DEC 2020	HEART CATH	Adverse Event	
08 JAN 2021	IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	Adverse Event	

US3822154

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:54:53

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:54:53

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

SAEID	USA-US126-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

SAEID	USA-US126-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/JAN/2021 16:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

SAEID	USA-US126-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/JAN/2021 21:02
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

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:06:53

Generated On: 10 Jun 2021 09:54:53

SAEID	USA-US126-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	28/JAN/2021 14:14
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

US3822154 (Prod: Tryon Medical Partners, PLLC)

US3822154

Form: Participant Creation

Generated On: 10 Jun 2021 09:54:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'US3822154'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:39:59

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Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:00

US3822154

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:40:01

US3822154

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:00

US3822154

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered 'SCRN'	System	10 Sep 2020 00:32:00

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:40:02

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User closed query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 10:08:17
Query 'Per CDM: Please complete this form.' answered with 'completed' (Site from DM).	Kelly Woodell (b) (4)	27 Aug 2020 00:42:32
User entered '63'	(b) (4) Kelly Woodell (b) (4)	27 Aug 2020 00:42:28
User opened query 'Per CDM: Please complete this form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:06:16

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'YEARS'	System	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '63'	System	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Male (M)'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'I'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:54:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	27 Aug 2020 00:42:28

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Aug 2020'	System	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2020'	System	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Amendment 2 (2)'	Kelly Woodell (b) (4)	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	17 Aug 2020 15:56:27

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:40:01

US3822154

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'I'	System	17 Aug 2020 15:56:36

US3822154

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:54:53

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Aug 2020 15:56:36

US3822154

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:54:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:20

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
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)	10 Sep 2020 00:34:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:34:51
Data point term sent to Coder	System	10 Sep 2020 00:33:28
User entered 'seasonal allergies'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2018'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 13:51:43
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	(b) (4) Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2018'	System	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2018'	System	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:32:39

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:35:52
Data point term sent to Coder	System	10 Sep 2020 00:34:28
User entered 'headaches'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2000'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2000'	System	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2000'	System	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:33:32

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:35:52
Data point term sent to Coder	System	10 Sep 2020 00:34:28
User entered 'sleep apnea'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2010'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2010'	System	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2010'	System	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:33:49

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:35:52
Data point term sent to Coder	System	10 Sep 2020 00:34:28
User entered 'Acne'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2015'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2015'	System	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2015'	System	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:34:14

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:36:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:36:53
Data point term sent to Coder	System	10 Sep 2020 00:35:29
User entered 'herpes simplex'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 1987'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 1987'	System	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '1987'	System	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:34:35

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
Data point term sent to Coder	System	10 Sep 2020 00:36:29
User entered 'depression'	Kelly Woodell (b) (4)	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2000'	Kelly Woodell (b) (4)	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2000'	System	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2000'	System	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:35:40

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
Data point term sent to Coder	System	10 Sep 2020 00:36:31
User entered 'anxiety'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2013'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2013'	System	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2013'	System	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:36:04

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
Data point term sent to Coder	System	10 Sep 2020 00:37:31
User entered 'erectile dysfunction'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2005'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2005'	System	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2005'	System	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:36:32

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Investigations, HLGt: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone decreased - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:37:55
Data point term sent to Coder	System	10 Sep 2020 00:37:32
User entered 'decreased testosterone'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 1992'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 1992'	System	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '1992'	System	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:36:50

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:39:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:39:43
Data point term sent to Coder	System	10 Sep 2020 00:38:32
User entered 'benign prostatic hyperplasia'	Kelly Woodell (b) (4)	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'un UNK 2016'	Kelly Woodell (b) (4)	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2016'	System	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2016'	System	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:37:46

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 00:39:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:39:43
Data point term sent to Coder	System	10 Sep 2020 00:38:32
User entered 'chronic kidney disease stage 3'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '11 May 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'May 2020'	System	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2020'	System	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:38:05

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Labile hypertension, LLT: Labile hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:40:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:40:45
Data point term sent to Coder	System	10 Sep 2020 00:39:34
User entered 'labile hypertension'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '06 May 2019'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'May 2019'	System	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2019'	System	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:38:33

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Chronic insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:40:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:40:44
Data point term sent to Coder	System	10 Sep 2020 00:39:36
User entered 'Chronic insomnia'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Nov 2018'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Nov 2018'	System	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2018'	System	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:38:56

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:40:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 00:40:45
Data point term sent to Coder	System	10 Sep 2020 00:39:34
User entered 'mixed hyperlipidemia'	Kelly Woodell (b) (4)	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Nov 2018'	Kelly Woodell (b) (4)	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Nov 2018'	System	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2018'	System	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:39:13

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User closed query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 17:28:03
Query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Per pt med hx, pt is not taking any medications' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 00:19:56
User opened query 'Per DM CLR: Please note that there is no ONGOING Con Med listed for treatment of this condition and ONGOING treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:33:22
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:41:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 00:41:47
Data point term sent to Coder	System	10 Sep 2020 00:40:36
User entered 'hypertension'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Nov 2018'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Nov 2018'	System	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2018'	System	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	10 Sep 2020 00:40:04

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Pollakiuria, LLT: Urination frequency of - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 23:59:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 23:59:51
Data point term sent to Coder	System	08 Dec 2020 23:58:30
User entered 'FREQUENT URINATION'	Krishna Shah (b) (4)	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'UN UNK 2016'	Krishna Shah (b) (4)	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Krishna Shah (b) (4)	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Krishna Shah (b) (4)	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2016'	System	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2016'	System	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	08 Dec 2020 23:58:01

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
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)	09 Dec 2020 00:01:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 00:01:05
Data point term sent to Coder	System	08 Dec 2020 23:59:31
User entered 'Seasonal allergies'	Krishna Shah (b) (4)	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'UN UNK 2018'	Krishna Shah (b) (4)	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Krishna Shah (b) (4)	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Krishna Shah (b) (4)	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Jan 2018'	System	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2018'	System	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	08 Dec 2020 23:59:17

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	(b) (4) Coders Import (b) (4) (b) (4)	24 Mar 2021 17:14:36
User coded data point as Term Coded data point by User: Coders System - version MedDRA\\23.0.	Coders Import (b) (4) (b) (4)	24 Mar 2021 17:14:36
Data point term sent to Coders	System	24 Mar 2021 17:14:05
User entered 'Botox Injection'	(b) (4), (b) (6)	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
User entered 'un Sep 2019'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User signature succeeded.	Christina Kennelly (b) (4)	26 Mar 2021 17:44:35
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered 'Sep 2019'	System	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered '2019'	System	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:54:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:01
User entered empty.	System	24 Mar 2021 17:13:43

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '11:17'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered '17 Aug 2020 11:17'	System	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '70' in	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41
DataPoint set to visible.	System	17 Aug 2020 15:56:36

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '214' lb	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41
DataPoint set to visible.	System	17 Aug 2020 15:56:36

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered '30.77001'	System	10 Sep 2020 00:40:41
DataPoint set to visible.	System	17 Aug 2020 15:56:36

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered 'kg/m2'	System	10 Sep 2020 00:40:41
DataPoint set to visible.	System	17 Aug 2020 15:56:36

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered 'bpm'	System	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered 'breaths/min'	System	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered 'mmHg'	System	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User entered 'mmHg'	System	10 Sep 2020 00:40:41

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:41:22

US3822154

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:41:22

US3822154

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:40:49

US3822154

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:13:55
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 17:39:08
User entered '17 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:40:49

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

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 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

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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 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

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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 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'I'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '0'	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:41:22
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:41:46

US3822154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:01

US3822154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:01

US3822154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:01

US3822154

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'VISIT1'	System	10 Sep 2020 00:42:01

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:40:04

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:00:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:00:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 15:40:04
User entered '104924' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:40:04

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:40:04

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 21:13:53
Query 'PER CDM: Please complete this section of the form.' answered with 'completed' (Site from DM).	Kelly Woodell (b) (4)	10 Sep 2020 00:42:18
User entered 'No (N)'	(b) (4) Kelly Woodell (b) (4)	10 Sep 2020 00:42:11
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Sep 2020 07:04:30

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:11

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:11

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:11

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:42:11

US3822154

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:53

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:38:40

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Pre-Dose (PREDOSE)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '11:17'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '17 Aug 2020 11:17'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '98.5' F	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '80'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'bpm'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '16'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'breaths/min'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '154'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '84'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered missing code ND - Not Done.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Post-Dose (POSTDOSE)'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '12:21'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '17 Aug 2020 12:21'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '99.2' F	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Oral (Oral)'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '85'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'bpm'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '18'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'breaths/min'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '140'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '80'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	10 Sep 2020 00:43:28

US3822154

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:31

US3822154

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:43:31

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '11:51'	Kelly Woodell (b) (4)	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '17 Aug 2020 11:51'	System	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Right Arm (RIGHT ARM)'	Kelly Woodell (b) (4)	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'ONCE'	System	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 15:57:06

US3822154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:47

US3822154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:47

US3822154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '11:29'	Kelly Woodell (b) (4)	10 Sep 2020 00:43:47

US3822154

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '17 Aug 2020 11:29'	System	10 Sep 2020 00:43:47

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '17 Aug 2020'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '11:38'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '17 Aug 2020 11:38'	System	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered empty.	System	10 Sep 2020 00:44:00

US3822154

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:03

US3822154

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	10 Sep 2020 00:44:03

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:15:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '592a22ca-f779-4fac-b4a5-d175d48da5c6' User entered 'Yes (Y)'	System	17 Aug 2020 16:16:23
	System	17 Aug 2020 16:16:23

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:03', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '592a22ca-f779-4fac-b4a5-d175d48da5c6' User entered '99.2'	System	17 Aug 2020 16:16:23
	System	17 Aug 2020 16:16:23

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:10', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '592a22ca-f779-4fac-b4a5-d175d48da5c6'	System	17 Aug 2020 16:16:23
User entered 'No (N)'	System	17 Aug 2020 16:16:23

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:18', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '592a22ca-f779-4fac-b4a5-d175d48da5c6'	System	17 Aug 2020 16:16:23
User entered '17 Aug 2020 12:16'	System	17 Aug 2020 16:16:23

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 12:11'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 14:41'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:40:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2cf6f272-605e-4c0c-97d9-34b3cd937e79' User entered 'Yes (Y)'	System	18 Aug 2020 01:41:20
	System	18 Aug 2020 01:41:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2cf6f272-605e-4c0c-97d9-34b3cd937e79' User entered '94.5'	System	18 Aug 2020 01:41:20
	System	18 Aug 2020 01:41:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2cf6f272-605e-4c0c-97d9-34b3cd937e79'	System	18 Aug 2020 01:41:20
User entered 'No (N)'	System	18 Aug 2020 01:41:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2cf6f272-605e-4c0c-97d9-34b3cd937e79' User entered '17 Aug 2020 21:41'	System	18 Aug 2020 01:41:20
	System	18 Aug 2020 01:41:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 15:36'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 2'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:14:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0c778140-a689-49a4-a9f3-7f7a1f70549a' User entered 'Yes (Y)'	System	19 Aug 2020 01:14:56
	System	19 Aug 2020 01:14:56

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:14:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0c778140-a689-49a4-a9f3-7f7a1f70549a' User entered '99.4'	System	19 Aug 2020 01:14:56
	System	19 Aug 2020 01:14:56

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:14:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0c778140-a689-49a4-a9f3-7f7a1f70549a' User entered 'Yes (Y)'	System	19 Aug 2020 01:14:56
	System	19 Aug 2020 01:14:56

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
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 'Patient took medication for medical history issue. Medication was not taken in relation to vaccine. ' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:59:20
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).	(b) (4), (b) (6)	21 Dec 2020 13:16:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:14:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0c778140-a689-49a4-a9f3-7f7a1f70549a'	System	19 Aug 2020 01:14:56
User entered '1'	System	19 Aug 2020 01:14:56

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:14:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0c778140-a689-49a4-a9f3-7f7a1f70549a' User entered '0'	System	19 Aug 2020 01:14:56
	System	19 Aug 2020 01:14:56

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:14:54', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0c778140-a689-49a4-a9f3-7f7a1f70549a' User entered '18 Aug 2020 21:14'	System	19 Aug 2020 01:14:56
	System	19 Aug 2020 01:14:56

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 3'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:33:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '57b89429-f0f3-40ef-bee3-fe68b3a7fbbf' User entered 'Yes (Y)'	System	20 Aug 2020 01:34:20
	System	20 Aug 2020 01:34:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:05', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '57b89429-f0f3-40ef-bee3-fe68b3a7fbbf' User entered '98.2'	System	20 Aug 2020 01:34:20
	System	20 Aug 2020 01:34:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:12', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '57b89429-f0f3-40ef-bee3-fe68b3a7fbbf'	System	20 Aug 2020 01:34:20
User entered 'No (N)'	System	20 Aug 2020 01:34:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:17', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '57b89429-f0f3-40ef-bee3-fe68b3a7fbbf' User entered '19 Aug 2020 21:34'	System	20 Aug 2020 01:34:20
	System	20 Aug 2020 01:34:20

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 4'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:40:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '215b1f36-deee-4f73-9eb7-931ba918d527' User entered 'Yes (Y)'	System	21 Aug 2020 02:41:05
	System	21 Aug 2020 02:41:05

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:40:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '215b1f36-deee-4f73-9eb7-931ba918d527' User entered '96.2'	System	21 Aug 2020 02:41:05
	System	21 Aug 2020 02:41:05

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:40:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '215b1f36-deee-4f73-9eb7-931ba918d527' User entered 'Yes (Y)'	System	21 Aug 2020 02:41:05
	System	21 Aug 2020 02:41:05

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
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 'Patient took medication for medical history issue. Medication was not taken in relation to vaccine. ' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 05:38:47
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).	(b) (4), (b) (6)	21 Dec 2020 13:16:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:40:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '215b1f36-deee-4f73-9eb7-931ba918d527'	System	21 Aug 2020 02:41:05
User entered '1'	System	21 Aug 2020 02:41:05

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:40:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '215b1f36-deee-4f73-9eb7-931ba918d527' User entered '0'	System	21 Aug 2020 02:41:05
	System	21 Aug 2020 02:41:05

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:03', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '215b1f36-deee-4f73-9eb7-931ba918d527' User entered '20 Aug 2020 22:41'	System	21 Aug 2020 02:41:05
	System	21 Aug 2020 02:41:05

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 5'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:05:54', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '01dcef3e-afe9-41b9-a377-ddf698aa6e19' User entered 'Yes (Y)'	System	22 Aug 2020 01:06:10
	System	22 Aug 2020 01:06:10

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:05:59', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '01dcef3e-afe9-41b9-a377-ddf698aa6e19' User entered '97.2'	System	22 Aug 2020 01:06:10
	System	22 Aug 2020 01:06:10

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:05', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '01dcef3e-afe9-41b9-a377-ddf698aa6e19'	System	22 Aug 2020 01:06:10
User entered 'No (N)'	System	22 Aug 2020 01:06:10

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '01dcef3e-afe9-41b9-a377-ddf698aa6e19' User entered '21 Aug 2020 21:06'	System	22 Aug 2020 01:06:10
	System	22 Aug 2020 01:06:10

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 6'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:10', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a1e429c7-57fd-4c1a-9eb1-03ddc4e6b24a' User entered 'Yes (Y)'	System	23 Aug 2020 02:07:45
	System	23 Aug 2020 02:07:45

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a1e429c7-57fd-4c1a-9eb1-03ddc4e6b24a' User entered '97.2'	System	23 Aug 2020 02:07:45
	System	23 Aug 2020 02:07:45

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:37', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a1e429c7-57fd-4c1a-9eb1-03ddc4e6b24a' User entered 'No (N)'	System	23 Aug 2020 02:07:45
	System	23 Aug 2020 02:07:45

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a1e429c7-57fd-4c1a-9eb1-03ddc4e6b24a' User entered '22 Aug 2020 22:07'	System	23 Aug 2020 02:07:45
	System	23 Aug 2020 02:07:45

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 7'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:31:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '81a8bd8d-352b-4f75-918a-b201ed6b6dd0' User entered 'Yes (Y)'	System	24 Aug 2020 01:32:21
	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:31:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '81a8bd8d-352b-4f75-918a-b201ed6b6dd0' User entered '97.1'	System	24 Aug 2020 01:32:21
	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:03', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '81a8bd8d-352b-4f75-918a-b201ed6b6dd0' User entered 'Yes (Y)'	System	24 Aug 2020 01:32:21
	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
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 'Patient took medication for medical history issue. Medication was not taken in relation to vaccine. ' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 05:39:04
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).	(b) (4), (b) (6)	21 Dec 2020 13:16:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '81a8bd8d-352b-4f75-918a-b201ed6b6dd0'	System	24 Aug 2020 01:32:21
User entered '1'	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '81a8bd8d-352b-4f75-918a-b201ed6b6dd0' User entered '0'	System	24 Aug 2020 01:32:21
	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:17', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '81a8bd8d-352b-4f75-918a-b201ed6b6dd0' User entered '23 Aug 2020 21:32'	System	24 Aug 2020 01:32:21
	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Aug 2020 01:32:21
User entered 'Day 8'	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:33:29', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f9b10ffb-cc73-4320-abe4-9dbadcaa28fc' User entered 'Yes (Y)'	System	25 Aug 2020 03:33:48
	System	25 Aug 2020 03:33:48

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:33:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f9b10ffb-cc73-4320-abe4-9dbadcaa28fc' User entered '99.6'	System	25 Aug 2020 03:33:48
	System	25 Aug 2020 03:33:48

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:33:37', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f9b10ffb-cc73-4320-abe4-9dbadcaa28fc' User entered 'No (N)'	System	25 Aug 2020 03:33:48
	System	25 Aug 2020 03:33:48

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:33:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f9b10ffb-cc73-4320-abe4-9dbadcaa28fc' User entered '24 Aug 2020 23:33'	System	25 Aug 2020 03:33:48
	System	25 Aug 2020 03:33:48

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 12:00'	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:36', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd064ef4e-65f3-494d-abed-a98661b43c16' User entered 'None (1)'	System	17 Aug 2020 16:17:03
	System	17 Aug 2020 16:17:03

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd064ef4e-65f3-494d-abed-a98661b43c16' User entered 'No (N)'	System	17 Aug 2020 16:17:03
	System	17 Aug 2020 16:17:03

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd064ef4e-65f3-494d-abed-a98661b43c16' User entered 'No (N)'	System	17 Aug 2020 16:17:03
	System	17 Aug 2020 16:17:03

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:16:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd064ef4e-65f3-494d-abed-a98661b43c16' User entered 'None (1)'	System	17 Aug 2020 16:17:03
	System	17 Aug 2020 16:17:03

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd064ef4e-65f3-494d-abad-a98661b43c16' User entered '17 Aug 2020 12:17'	System	17 Aug 2020 16:17:03
	System	17 Aug 2020 16:17:03

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 12:11'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 14:41'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1937e687-dc0d-4cb7-9302-e903fa6863c9' User entered 'None (1)'	System	18 Aug 2020 01:42:58
	System	18 Aug 2020 01:42:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1937e687-dc0d-4cb7-9302-e903fa6863c9' User entered 'No (N)'	System	18 Aug 2020 01:42:58
	System	18 Aug 2020 01:42:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1937e687-dc0d-4cb7-9302-e903fa6863c9' User entered 'No (N)'	System	18 Aug 2020 01:42:58
	System	18 Aug 2020 01:42:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1937e687-dc0d-4cb7-9302-e903fa6863c9' User entered 'None (1)'	System	18 Aug 2020 01:42:58
	System	18 Aug 2020 01:42:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:55', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1937e687-dc0d-4cb7-9302-e903fa6863c9' User entered '17 Aug 2020 21:42'	System	18 Aug 2020 01:42:58
	System	18 Aug 2020 01:42:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 15:36'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 2'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1fa597a3-3911-4bf9-bc6c-0d0546c1bce7'	System	19 Aug 2020 01:15:23
User entered 'None (1)'	System	19 Aug 2020 01:15:23

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:03', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1fa597a3-3911-4bf9-bc6c-0d0546c1bce7' User entered 'No (N)'	System	19 Aug 2020 01:15:23
	System	19 Aug 2020 01:15:23

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:09', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1fa597a3-3911-4bf9-bc6c-0d0546c1bce7' User entered 'No (N)'	System	19 Aug 2020 01:15:23
	System	19 Aug 2020 01:15:23

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:15', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1fa597a3-3911-4bf9-bc6c-0d0546c1bce7' User entered 'None (1)'	System	19 Aug 2020 01:15:23
	System	19 Aug 2020 01:15:23

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1fa597a3-3911-4bf9-bc6c-0d0546c1bce7' User entered '18 Aug 2020 21:15'	System	19 Aug 2020 01:15:23
	System	19 Aug 2020 01:15:23

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 3'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fe0823e5-507a-45f4-825c-ca7dfce6f49e' User entered 'None (1)'	System	20 Aug 2020 01:34:58
	System	20 Aug 2020 01:34:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:31', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fe0823e5-507a-45f4-825c-ca7dfce6f49e' User entered 'No (N)'	System	20 Aug 2020 01:34:58
	System	20 Aug 2020 01:34:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:37', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fe0823e5-507a-45f4-825c-ca7dfce6f49e' User entered 'No (N)'	System	20 Aug 2020 01:34:58
	System	20 Aug 2020 01:34:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fe0823e5-507a-45f4-825c-ca7dfce6f49e' User entered 'None (1)'	System	20 Aug 2020 01:34:58
	System	20 Aug 2020 01:34:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:34:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fe0823e5-507a-45f4-825c-ca7dfce6f49e' User entered '19 Aug 2020 21:34'	System	20 Aug 2020 01:34:58
	System	20 Aug 2020 01:34:58

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 4'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '3c1544f5-4f21-4830-8286-3d75bc3ccc9b' User entered 'None (1)'	System	21 Aug 2020 02:41:26
	System	21 Aug 2020 02:41:26

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '3c1544f5-4f21-4830-8286-3d75bc3ccc9b' User entered 'No (N)'	System	21 Aug 2020 02:41:26
	System	21 Aug 2020 02:41:26

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:16', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '3c1544f5-4f21-4830-8286-3d75bc3ccc9b' User entered 'No (N)'	System	21 Aug 2020 02:41:26
	System	21 Aug 2020 02:41:26

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:18', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '3c1544f5-4f21-4830-8286-3d75bc3ccc9b' User entered 'None (1)'	System	21 Aug 2020 02:41:26
	System	21 Aug 2020 02:41:26

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:23', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '3c1544f5-4f21-4830-8286-3d75bc3ccc9b' User entered '20 Aug 2020 22:41'	System	21 Aug 2020 02:41:26
	System	21 Aug 2020 02:41:26

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 5'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:14', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '964486f1-0471-4cc9-8bac-78703538058d' User entered 'None (1)'	System	22 Aug 2020 01:06:30
	System	22 Aug 2020 01:06:30

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:17', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '964486f1-0471-4cc9-8bac-78703538058d' User entered 'No (N)'	System	22 Aug 2020 01:06:30
	System	22 Aug 2020 01:06:30

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '964486f1-0471-4cc9-8bac-78703538058d' User entered 'No (N)'	System	22 Aug 2020 01:06:30
	System	22 Aug 2020 01:06:30

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:24', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '964486f1-0471-4cc9-8bac-78703538058d' User entered 'None (1)'	System	22 Aug 2020 01:06:30
	System	22 Aug 2020 01:06:30

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '964486f1-0471-4cc9-8bac-78703538058d' User entered '21 Aug 2020 21:06'	System	22 Aug 2020 01:06:30
	System	22 Aug 2020 01:06:30

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 6'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:47', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5ea71207-1370-4478-bc8c-235b6668a7d3' User entered 'None (1)'	System	23 Aug 2020 02:08:09
	System	23 Aug 2020 02:08:09

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:55', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5ea71207-1370-4478-bc8c-235b6668a7d3' User entered 'No (N)'	System	23 Aug 2020 02:08:09
	System	23 Aug 2020 02:08:09

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:07:59', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5ea71207-1370-4478-bc8c-235b6668a7d3' User entered 'No (N)'	System	23 Aug 2020 02:08:09
	System	23 Aug 2020 02:08:09

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5ea71207-1370-4478-bc8c-235b6668a7d3'	System	23 Aug 2020 02:08:09
User entered 'None (1)'	System	23 Aug 2020 02:08:09

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:06', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5ea71207-1370-4478-bc8c-235b6668a7d3' User entered '22 Aug 2020 22:08'	System	23 Aug 2020 02:08:09
	System	23 Aug 2020 02:08:09

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 7'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '80b5eff4-d5c4-4c64-ac99-feb27da4c973' User entered 'None (1)'	System	24 Aug 2020 01:33:10
	System	24 Aug 2020 01:33:10

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '80b5eff4-d5c4-4c64-ac99-feb27da4c973' User entered 'No (N)'	System	24 Aug 2020 01:33:10
	System	24 Aug 2020 01:33:10

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:32:33', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '80b5eff4-d5c4-4c64-ac99-feb27da4c973' User entered 'No (N)'	System	24 Aug 2020 01:33:10
	System	24 Aug 2020 01:33:10

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '80b5eff4-d5c4-4c64-ac99-feb27da4c973' User entered 'None (1)'	System	24 Aug 2020 01:33:10
	System	24 Aug 2020 01:33:10

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:05', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '80b5eff4-d5c4-4c64-ac99-feb27da4c973'	System	24 Aug 2020 01:33:10
User entered '23 Aug 2020 21:33'	System	24 Aug 2020 01:33:10

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:09', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'None (0)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:12', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'None (0)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:14', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'None (0)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:17', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'None (0)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:19', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'None (0)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'None (0)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:26', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered 'No (N)'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T12:17:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '71b14107-0eae-46b0-9cf6-5190ab2944d0' User entered '17 Aug 2020 12:17'	System	17 Aug 2020 16:17:35
	System	17 Aug 2020 16:17:35

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 12:11'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 14:41'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:20', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725' User entered 'None (0)'	System	18 Aug 2020 01:42:21
	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:42', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bcccc725'	System	18 Aug 2020 01:42:21
User entered 'Some interference with activity (2)'	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725'	System	18 Aug 2020 01:42:21
User entered 'No interference with activity (1)'	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725'	System	18 Aug 2020 01:42:21
User entered 'No interference with activity (1)'	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:41:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725' User entered 'None (0)'	System	18 Aug 2020 01:42:21
	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725' User entered 'None (0)'	System	18 Aug 2020 01:42:21
	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:05', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725' User entered 'No (N)'	System	18 Aug 2020 01:42:21
	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-17T21:42:18', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60e70bc0-5553-4401-9ac6-0cc9bccccd725' User entered '17 Aug 2020 21:42'	System	18 Aug 2020 01:42:21
	System	18 Aug 2020 01:42:21

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Aug 2020 15:36'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 2'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered 'None (0)'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a'	System	19 Aug 2020 01:16:05
User entered 'Some interference with activity (2)'	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered 'No interference with activity (1)'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered 'Some interference with activity (2)'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered 'None (0)'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:52', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered 'None (0)'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:15:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered 'No (N)'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-18T21:16:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e2536d4d-e038-4dc3-86cb-3303b7a7807a' User entered '18 Aug 2020 21:16'	System	19 Aug 2020 01:16:05
	System	19 Aug 2020 01:16:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 3'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:25', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349' User entered 'None (0)'	System	20 Aug 2020 01:36:12
	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:35', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349'	System	20 Aug 2020 01:36:12
User entered 'Some interference with activity (2)'	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:42', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349'	System	20 Aug 2020 01:36:12
User entered 'No interference with activity (1)'	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349' User entered 'No interference with activity (1)'	System	20 Aug 2020 01:36:12
	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:53', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349' User entered 'None (0)'	System	20 Aug 2020 01:36:12
	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:55', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349' User entered 'None (0)'	System	20 Aug 2020 01:36:12
	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:35:59', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349' User entered 'No (N)'	System	20 Aug 2020 01:36:12
	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-19T21:36:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2bf7bfea-b8ea-4c5d-8c89-775b0eef1349' User entered '19 Aug 2020 21:36'	System	20 Aug 2020 01:36:12
	System	20 Aug 2020 01:36:12

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 4'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:29', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4'	System	21 Aug 2020 02:42:05
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4'	System	21 Aug 2020 02:42:05
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4'	System	21 Aug 2020 02:42:05
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4'	System	21 Aug 2020 02:42:05
User entered 'No interference with activity (1)'	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:52', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4' User entered 'None (0)'	System	21 Aug 2020 02:42:05
	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:55', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4' User entered 'None (0)'	System	21 Aug 2020 02:42:05
	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:41:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4' User entered 'No (N)'	System	21 Aug 2020 02:42:05
	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-20T22:42:03', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '15cf9c2d-b0b7-4d27-b0c9-a943774fccb4' User entered '20 Aug 2020 22:42'	System	21 Aug 2020 02:42:05
	System	21 Aug 2020 02:42:05

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 5'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'None (0)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'No interference with activity (1)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'None (0)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:53', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'No interference with activity (1)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:55', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'None (0)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:06:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'None (0)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:07:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered 'No (N)'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-21T21:07:06', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f46acfb3-2823-49c6-a29a-31faf3316090' User entered '21 Aug 2020 21:07'	System	22 Aug 2020 01:07:09
	System	22 Aug 2020 01:07:09

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 6'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'None (0)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'None (0)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:24', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'None (0)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'No interference with activity (1)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:30', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'None (0)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'None (0)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:35', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered 'No (N)'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-22T22:08:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c9f3cfa4-ce5a-4e94-b1a6-ac47784899f3' User entered '22 Aug 2020 22:08'	System	23 Aug 2020 02:08:44
	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 7'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'None (0)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:17', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'No interference with activity (1)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:20', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'None (0)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:23', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'No interference with activity (1)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:26', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'None (0)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'None (0)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:30', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered 'No (N)'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-23T21:33:42', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '47e6f719-c553-4063-a11a-198168540026' User entered '23 Aug 2020 21:33'	System	24 Aug 2020 01:33:44
	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Aug 2020 01:33:44
User entered 'Day 8'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:34:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4efecfeb-7a26-4f23-9780-ee2d186b5875'	System	25 Aug 2020 03:34:09
User entered 'No interference with activity (1)'	System	25 Aug 2020 03:34:09

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:34:07', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4efecfeb-7a26-4f23-9780-ee2d186b5875' User entered '24 Aug 2020 23:34'	System	25 Aug 2020 03:34:09
	System	25 Aug 2020 03:34:09

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 12:00'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Aug 2020 01:33:44
User entered 'Day 9'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-25T22:04:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'be2b8dfb-52d6-48ad-b11f-9c6ac2807260' User entered 'None (0)'	System	26 Aug 2020 02:04:55
	System	26 Aug 2020 02:04:55

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-25T22:04:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'be2b8dfb-52d6-48ad-b11f-9c6ac2807260' User entered '25 Aug 2020 22:04'	System	26 Aug 2020 02:04:55
	System	26 Aug 2020 02:04:55

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	23 Aug 2020 02:08:44
User entered 'Day 8'	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:34:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '364e8f68-1ff2-48f7-bb38-d7bda9a4271c' User entered 'No interference with activity (1)'	System	25 Aug 2020 03:34:15
	System	25 Aug 2020 03:34:15

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:34:14', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '364e8f68-1ff2-48f7-bb38-d7bda9a4271c' User entered '24 Aug 2020 23:34'	System	25 Aug 2020 03:34:15
	System	25 Aug 2020 03:34:15

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Aug 2020 01:33:44
User entered 'Day 9'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-25T22:04:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '19542a95-f31b-4492-8559-d72f70d6dfbb' User entered 'None (0)'	System	26 Aug 2020 02:05:09
	System	26 Aug 2020 02:05:09

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-25T22:04:53', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '19542a95-f31b-4492-8559-d72f70d6dfbb' User entered '25 Aug 2020 22:04'	System	26 Aug 2020 02:05:09
	System	26 Aug 2020 02:05:09

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 01:33:44

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	23 Aug 2020 02:08:44
User entered 'Day 8'	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:34:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dcd42a2b-0fc1-442a-9662-ffae078df24a' User entered 'Yes (Y)'	System	25 Aug 2020 03:34:36
	System	25 Aug 2020 03:34:36

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-24T23:34:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dcd42a2b-0fc1-442a-9662-ffae078df24a' User entered '24 Aug 2020 23:34'	System	25 Aug 2020 03:34:36
	System	25 Aug 2020 03:34:36

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 02:08:44

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Aug 2020 01:32:21
User entered 'Day 9'	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-25T22:04:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '83f481a1-a471-4c41-bec3-5fe08d3697a9' User entered 'No (N)'	System	26 Aug 2020 02:05:15
	System	26 Aug 2020 02:05:15

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-08-25T22:04:59', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '83f481a1-a471-4c41-bec3-5fe08d3697a9' User entered '25 Aug 2020 22:04'	System	26 Aug 2020 02:05:15
	System	26 Aug 2020 02:05:15

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 01:32:21

US3822154

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 01:32:21

US3822154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:46

US3822154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 11:21:54
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as is' (Site from System).	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:45:02
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 00:44:46
User entered '28 Aug 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:44:46

US3822154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	10 Sep 2020 00:44:46

US3822154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:44:46

US3822154

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:45:06

US3822154

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	10 Sep 2020 00:45:06

US3822154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:45:21

US3822154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 11:22:22
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as is' (Site from System).	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:45:32
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Sep 2020 00:45:21
User entered '04 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	10 Sep 2020 00:45:21

US3822154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	10 Sep 2020 00:45:21

US3822154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered empty.	Kelly Woodell (b) (4)	10 Sep 2020 00:45:21

US3822154

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	10 Sep 2020 00:45:43

US3822154

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	10 Sep 2020 00:45:43

US3822154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	14 Sep 2020 17:38:43

US3822154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 20:22:09
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as is' (Site from System).	Kelly Woodell (b) (4) (b) (4)	14 Sep 2020 17:38:52
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 17:38:43
User entered '11 Sep 2020'	Kelly Woodell (b) (4) (b) (4)	14 Sep 2020 17:38:43

US3822154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	14 Sep 2020 17:38:43

US3822154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered empty.	Kelly Woodell (b) (4)	14 Sep 2020 17:38:43

US3822154

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	14 Sep 2020 17:38:57

US3822154

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	14 Sep 2020 17:38:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User closed query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 19OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 08:04:57
Query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 19OCT2020, per GCL. Please clarify and update as appropriate. ' answered with 'already entered' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:48:06
User opened query 'Per GCL Lab Reconciliation: Immunogenicity form is blank for Visit 3 Day 57, however, there is a Visit 3 Day 57 Immunogenicity sample with a Collection Date of 19OCT2020, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:13:42
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	14 Sep 2020 17:39:08

US3822154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Sep 2020'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:08

US3822154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:08

US3822154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'VISIT2'	System	14 Sep 2020 17:39:08

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '13:05'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '14 Sep 2020 13:05'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '99.3' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '92'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'bpm'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'breaths/min'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '146'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '82'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14:05'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '14 Sep 2020 14:05'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '94'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'bpm'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'breaths/min'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '165'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '100'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	15 Oct 2020 00:21:13

US3822154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:14

US3822154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	14 Sep 2020 17:39:14

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Sep 2020'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '13:35'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '14 Sep 2020 13:35'	System	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Right Arm (RIGHT ARM)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'ONCE'	System	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 17:39:29

US3822154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 16OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 12:34:08
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 16OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'already entered' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 14:47:50
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 16OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 17:23:33
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	14 Sep 2020 17:39:42

US3822154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Sep 2020'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:42

US3822154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '13:14'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:42

US3822154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '14 Sep 2020 13:14'	System	14 Sep 2020 17:39:42

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '14 Sep 2020'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '13:23'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '14 Sep 2020 13:23'	System	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Kelly Woodell (b) (4)	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered empty.	System	14 Sep 2020 17:39:57

US3822154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	14 Sep 2020 17:40:02

US3822154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	14 Sep 2020 17:40:02

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:57:42', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e5aabee6-c183-422a-8256-2ed27a62ecb8' User entered 'Yes (Y)'	System	14 Sep 2020 17:58:03
	System	14 Sep 2020 17:58:03

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:57:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e5aabee6-c183-422a-8256-2ed27a62ecb8' User entered '98.5'	System	14 Sep 2020 17:58:03
	System	14 Sep 2020 17:58:03

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:57:52', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e5aabee6-c183-422a-8256-2ed27a62ecb8'	System	14 Sep 2020 17:58:03
User entered 'No (N)'	System	14 Sep 2020 17:58:03

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:57:59', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'e5aabee6-c183-422a-8256-2ed27a62ecb8' User entered '14 Sep 2020 13:57'	System	14 Sep 2020 17:58:03
	System	14 Sep 2020 17:58:03

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 13:55'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 16:25'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:23:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'b8ed598a-829f-4030-841b-dbc67f616a3a' User entered 'Yes (Y)'	System	15 Sep 2020 00:24:16
	System	15 Sep 2020 00:24:16

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'b8ed598a-829f-4030-841b-dbc67f616a3a' User entered '97.0'	System	15 Sep 2020 00:24:16
	System	15 Sep 2020 00:24:16

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'b8ed598a-829f-4030-841b-dbc67f616a3a' User entered 'No (N)'	System	15 Sep 2020 00:24:16
	System	15 Sep 2020 00:24:16

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'b8ed598a-829f-4030-841b-dbc67f616a3a' User entered '14 Sep 2020 20:24'	System	15 Sep 2020 00:24:16
	System	15 Sep 2020 00:24:16

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 17:20'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 2'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:23', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '858efb66-90a8-4828-82a9-271279e68a65' User entered 'Yes (Y)'	System	16 Sep 2020 00:44:52
	System	16 Sep 2020 00:44:52

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '858efb66-90a8-4828-82a9-271279e68a65' User entered '97.4'	System	16 Sep 2020 00:44:52
	System	16 Sep 2020 00:44:52

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '858efb66-90a8-4828-82a9-271279e68a65'	System	16 Sep 2020 00:44:52
User entered 'Yes (Y)'	System	16 Sep 2020 00:44:52

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
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 'conmed has been added' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:58:25
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).	(b) (4), (b) (6)	21 Dec 2020 13:21:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '858efb66-90a8-4828-82a9-271279e68a65'	System	16 Sep 2020 00:44:52
User entered '1'	System	16 Sep 2020 00:44:52

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '858efb66-90a8-4828-82a9-271279e68a65' User entered '0'	System	16 Sep 2020 00:44:52
	System	16 Sep 2020 00:44:52

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '858efb66-90a8-4828-82a9-271279e68a65' User entered '15 Sep 2020 20:44'	System	16 Sep 2020 00:44:52
	System	16 Sep 2020 00:44:52

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 3'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:42:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5159cd90-6f55-48bf-afef-65c7e97a12b2' User entered 'Yes (Y)'	System	17 Sep 2020 00:43:44
	System	17 Sep 2020 00:43:44

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:42:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5159cd90-6f55-48bf-afef-65c7e97a12b2' User entered '97.3'	System	17 Sep 2020 00:43:44
	System	17 Sep 2020 00:43:44

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:22', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5159cd90-6f55-48bf-afef-65c7e97a12b2'	System	17 Sep 2020 00:43:44
User entered 'Yes (Y)'	System	17 Sep 2020 00:43:44

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
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 'Conmed has been added' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 05:58:36
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).	(b) (4), (b) (6)	21 Dec 2020 13:22:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:31', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5159cd90-6f55-48bf-afef-65c7e97a12b2'	System	17 Sep 2020 00:43:44
User entered '1'	System	17 Sep 2020 00:43:44

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:31', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5159cd90-6f55-48bf-afef-65c7e97a12b2' User entered '0'	System	17 Sep 2020 00:43:44
	System	17 Sep 2020 00:43:44

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5159cd90-6f55-48bf-afef-65c7e97a12b2' User entered '16 Sep 2020 20:43'	System	17 Sep 2020 00:43:44
	System	17 Sep 2020 00:43:44

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 4'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:43:52', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '09004792-fbb8-47b4-a22c-47cbb97bc086' User entered 'Yes (Y)'	System	18 Sep 2020 02:44:25
	System	18 Sep 2020 02:44:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:43:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '09004792-fbb8-47b4-a22c-47cbb97bc086' User entered '97.3'	System	18 Sep 2020 02:44:25
	System	18 Sep 2020 02:44:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '09004792-fbb8-47b4-a22c-47cbb97bc086' User entered 'No (N)'	System	18 Sep 2020 02:44:25
	System	18 Sep 2020 02:44:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:06', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '09004792-fbb8-47b4-a22c-47cbb97bc086' User entered '17 Sep 2020 22:44'	System	18 Sep 2020 02:44:25
	System	18 Sep 2020 02:44:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 5'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:12', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '056300f5-3de7-482d-bd60-d5d42bfc30ad' User entered 'Yes (Y)'	System	19 Sep 2020 03:25:49
	System	19 Sep 2020 03:25:49

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '056300f5-3de7-482d-bd60-d5d42bfc30ad' User entered '96.9'	System	19 Sep 2020 03:25:49
	System	19 Sep 2020 03:25:49

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:24', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '056300f5-3de7-482d-bd60-d5d42bfc30ad' User entered 'No (N)'	System	19 Sep 2020 03:25:49
	System	19 Sep 2020 03:25:49

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '056300f5-3de7-482d-bd60-d5d42bfc30ad' User entered '18 Sep 2020 23:25'	System	19 Sep 2020 03:25:49
	System	19 Sep 2020 03:25:49

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 6'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:48:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1e9966e9-688f-43fb-a660-1de8a69f9888' User entered 'Yes (Y)'	System	20 Sep 2020 00:49:25
	System	20 Sep 2020 00:49:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:49:03', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1e9966e9-688f-43fb-a660-1de8a69f9888' User entered '98.3'	System	20 Sep 2020 00:49:25
	System	20 Sep 2020 00:49:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:49:16', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1e9966e9-688f-43fb-a660-1de8a69f9888'	System	20 Sep 2020 00:49:25
User entered 'No (N)'	System	20 Sep 2020 00:49:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:49:23', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1e9966e9-688f-43fb-a660-1de8a69f9888' User entered '19 Sep 2020 20:49'	System	20 Sep 2020 00:49:25
	System	20 Sep 2020 00:49:25

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 7'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:13:17', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '213af9c7-bac6-43ba-a7b5-fcd41022f2e1' User entered 'Yes (Y)'	System	21 Sep 2020 00:14:36
	System	21 Sep 2020 00:14:36

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:28', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '213af9c7-bac6-43ba-a7b5-fcd41022f2e1' User entered '97.7'	System	21 Sep 2020 00:14:36
	System	21 Sep 2020 00:14:36

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:30', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '213af9c7-bac6-43ba-a7b5-fcd41022f2e1' User entered 'No (N)'	System	21 Sep 2020 00:14:36
	System	21 Sep 2020 00:14:36

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:33', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '213af9c7-bac6-43ba-a7b5-fcd41022f2e1' User entered '20 Sep 2020 20:14'	System	21 Sep 2020 00:14:36
	System	21 Sep 2020 00:14:36

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:20', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '504ea162-c923-4082-9af3-58477cb710e0' User entered 'None (1)'	System	14 Sep 2020 17:58:47
	System	14 Sep 2020 17:58:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '504ea162-c923-4082-9af3-58477cb710e0' User entered 'No (N)'	System	14 Sep 2020 17:58:47
	System	14 Sep 2020 17:58:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '504ea162-c923-4082-9af3-58477cb710e0' User entered 'No (N)'	System	14 Sep 2020 17:58:47
	System	14 Sep 2020 17:58:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:42', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '504ea162-c923-4082-9af3-58477cb710e0' User entered 'None (1)'	System	14 Sep 2020 17:58:47
	System	14 Sep 2020 17:58:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '504ea162-c923-4082-9af3-58477cb710e0' User entered '14 Sep 2020 13:58'	System	14 Sep 2020 17:58:47
	System	14 Sep 2020 17:58:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 13:55'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 16:25'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:23', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'efa1835b-da2d-4386-9f80-147c9f16257d' User entered 'None (1)'	System	15 Sep 2020 00:24:47
	System	15 Sep 2020 00:24:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:29', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'efa1835b-da2d-4386-9f80-147c9f16257d' User entered 'No (N)'	System	15 Sep 2020 00:24:47
	System	15 Sep 2020 00:24:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:31', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'efa1835b-da2d-4386-9f80-147c9f16257d' User entered 'No (N)'	System	15 Sep 2020 00:24:47
	System	15 Sep 2020 00:24:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'efa1835b-da2d-4386-9f80-147c9f16257d' User entered 'None (1)'	System	15 Sep 2020 00:24:47
	System	15 Sep 2020 00:24:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'efa1835b-da2d-4386-9f80-147c9f16257d' User entered '14 Sep 2020 20:24'	System	15 Sep 2020 00:24:47
	System	15 Sep 2020 00:24:47

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 17:20'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 2'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:54', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8ceae73a-66fb-4ae6-b6e9-dc5955ee4b08'	System	16 Sep 2020 00:45:22
User entered 'None (1)'	System	16 Sep 2020 00:45:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:44:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8ceae73a-66fb-4ae6-b6e9-dc5955ee4b08' User entered 'No (N)'	System	16 Sep 2020 00:45:22
	System	16 Sep 2020 00:45:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:45:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8ceae73a-66fb-4ae6-b6e9-dc5955ee4b08' User entered 'No (N)'	System	16 Sep 2020 00:45:22
	System	16 Sep 2020 00:45:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:45:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8ceae73a-66fb-4ae6-b6e9-dc5955ee4b08' User entered 'None (1)'	System	16 Sep 2020 00:45:22
	System	16 Sep 2020 00:45:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:45:20', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8ceae73a-66fb-4ae6-b6e9-dc5955ee4b08' User entered '15 Sep 2020 20:45'	System	16 Sep 2020 00:45:22
	System	16 Sep 2020 00:45:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 3'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'aec82623-cedb-41de-a0a2-d9832e130823' User entered 'None (1)'	System	17 Sep 2020 00:44:03
	System	17 Sep 2020 00:44:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'aec82623-cedb-41de-a0a2-d9832e130823' User entered 'No (N)'	System	17 Sep 2020 00:44:03
	System	17 Sep 2020 00:44:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:53', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'aec82623-cedb-41de-a0a2-d9832e130823' User entered 'No (N)'	System	17 Sep 2020 00:44:03
	System	17 Sep 2020 00:44:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:43:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'aec82623-cedb-41de-a0a2-d9832e130823' User entered 'None (1)'	System	17 Sep 2020 00:44:03
	System	17 Sep 2020 00:44:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'aec82623-cedb-41de-a0a2-d9832e130823' User entered '16 Sep 2020 20:44'	System	17 Sep 2020 00:44:03
	System	17 Sep 2020 00:44:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 4'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7f8015c3-78d0-4ef6-889a-cb53a43e47fb' User entered 'None (1)'	System	18 Sep 2020 02:44:34
	System	18 Sep 2020 02:44:34

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:16', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7f8015c3-78d0-4ef6-889a-cb53a43e47fb' User entered 'No (N)'	System	18 Sep 2020 02:44:34
	System	18 Sep 2020 02:44:34

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:18', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7f8015c3-78d0-4ef6-889a-cb53a43e47fb' User entered 'No (N)'	System	18 Sep 2020 02:44:34
	System	18 Sep 2020 02:44:34

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7f8015c3-78d0-4ef6-889a-cb53a43e47fb' User entered 'None (1)'	System	18 Sep 2020 02:44:34
	System	18 Sep 2020 02:44:34

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:25', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7f8015c3-78d0-4ef6-889a-cb53a43e47fb' User entered '17 Sep 2020 22:44'	System	18 Sep 2020 02:44:34
	System	18 Sep 2020 02:44:34

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 5'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c5c5369c-3b71-4d2b-ae07-9401665cdd94'	System	19 Sep 2020 03:26:03
User entered 'None (1)'	System	19 Sep 2020 03:26:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c5c5369c-3b71-4d2b-ae07-9401665cdd94' User entered 'No (N)'	System	19 Sep 2020 03:26:03
	System	19 Sep 2020 03:26:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c5c5369c-3b71-4d2b-ae07-9401665cdd94' User entered 'No (N)'	System	19 Sep 2020 03:26:03
	System	19 Sep 2020 03:26:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:42', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c5c5369c-3b71-4d2b-ae07-9401665cdd94' User entered 'None (1)'	System	19 Sep 2020 03:26:03
	System	19 Sep 2020 03:26:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c5c5369c-3b71-4d2b-ae07-9401665cdd94' User entered '18 Sep 2020 23:25'	System	19 Sep 2020 03:26:03
	System	19 Sep 2020 03:26:03

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 6'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:49:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '052836a2-c1a0-4e6f-bb1e-123ad39d85ee' User entered 'None (1)'	System	20 Sep 2020 00:50:22
	System	20 Sep 2020 00:50:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:49:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '052836a2-c1a0-4e6f-bb1e-123ad39d85ee' User entered 'No (N)'	System	20 Sep 2020 00:50:22
	System	20 Sep 2020 00:50:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '052836a2-c1a0-4e6f-bb1e-123ad39d85ee' User entered 'No (N)'	System	20 Sep 2020 00:50:22
	System	20 Sep 2020 00:50:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '052836a2-c1a0-4e6f-bb1e-123ad39d85ee' User entered 'None (1)'	System	20 Sep 2020 00:50:22
	System	20 Sep 2020 00:50:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:19', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '052836a2-c1a0-4e6f-bb1e-123ad39d85ee' User entered '19 Sep 2020 20:50'	System	20 Sep 2020 00:50:22
	System	20 Sep 2020 00:50:22

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 7'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:37', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ef6840cb-1a56-4b49-b756-bc437b626189' User entered 'None (1)'	System	21 Sep 2020 00:14:49
	System	21 Sep 2020 00:14:49

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ef6840cb-1a56-4b49-b756-bc437b626189' User entered 'No (N)'	System	21 Sep 2020 00:14:49
	System	21 Sep 2020 00:14:49

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ef6840cb-1a56-4b49-b756-bc437b626189' User entered 'No (N)'	System	21 Sep 2020 00:14:49
	System	21 Sep 2020 00:14:49

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ef6840cb-1a56-4b49-b756-bc437b626189' User entered 'None (1)'	System	21 Sep 2020 00:14:49
	System	21 Sep 2020 00:14:49

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ef6840cb-1a56-4b49-b756-bc437b626189' User entered '20 Sep 2020 20:14'	System	21 Sep 2020 00:14:49
	System	21 Sep 2020 00:14:49

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'None (0)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:53', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'None (0)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:58:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'None (0)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:59:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'None (0)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:59:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'None (0)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:59:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'None (0)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:59:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered 'No (N)'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T13:59:12', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd066c5ec-9654-405a-b31f-29111b852b19' User entered '14 Sep 2020 13:59'	System	14 Sep 2020 17:59:15
	System	14 Sep 2020 17:59:15

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 13:55'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 16:25'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'No interference with activity (1)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:24:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'Some interference with activity (2)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:25:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'Some interference with activity (2)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:25:31', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'Some interference with activity (2)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:25:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'None (0)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:25:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'None (0)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:25:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered 'No (N)'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-14T20:25:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5feb59ef-c9d7-40a4-88b1-d19079e5fedf' User entered '14 Sep 2020 20:25'	System	15 Sep 2020 00:25:51
	System	15 Sep 2020 00:25:51

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '14 Sep 2020 17:20'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 2'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:45:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459'	System	16 Sep 2020 00:47:09
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:45:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459'	System	16 Sep 2020 00:47:09
User entered 'Some interference with activity (2)'	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:46:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459'	System	16 Sep 2020 00:47:09
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:46:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459'	System	16 Sep 2020 00:47:09
User entered 'Some interference with activity (2)'	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:46:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459'	System	16 Sep 2020 00:47:09
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:46:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459' User entered 'None (0)'	System	16 Sep 2020 00:47:09
	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:46:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459' User entered 'No (N)'	System	16 Sep 2020 00:47:09
	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-15T20:47:06', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '50c0ec68-ccad-4595-9c38-149fe339f459' User entered '15 Sep 2020 20:47'	System	16 Sep 2020 00:47:09
	System	16 Sep 2020 00:47:09

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 3'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c'	System	17 Sep 2020 00:45:10
User entered 'No interference with activity (1)'	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:15', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c'	System	17 Sep 2020 00:45:10
User entered 'Some interference with activity (2)'	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c'	System	17 Sep 2020 00:45:10
User entered 'Some interference with activity (2)'	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c' User entered 'Some interference with activity (2)'	System	17 Sep 2020 00:45:10
	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c' User entered 'None (0)'	System	17 Sep 2020 00:45:10
	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:44:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c' User entered 'None (0)'	System	17 Sep 2020 00:45:10
	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:45:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c' User entered 'No (N)'	System	17 Sep 2020 00:45:10
	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-16T20:45:07', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '60f1853a-752c-4606-a415-32035fdf493c' User entered '16 Sep 2020 20:45'	System	17 Sep 2020 00:45:10
	System	17 Sep 2020 00:45:10

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 4'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'None (0)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:35', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'No interference with activity (1)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:39', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'No interference with activity (1)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'No interference with activity (1)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'None (0)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'None (0)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered 'No (N)'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-17T22:44:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ee893939-bda2-4dfd-88a5-f188b080928e' User entered '17 Sep 2020 22:44'	System	18 Sep 2020 02:45:01
	System	18 Sep 2020 02:45:01

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 5'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:25:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered 'None (0)'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b'	System	19 Sep 2020 03:26:27
User entered 'No interference with activity (1)'	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:10', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered 'None (0)'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:12', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered 'No interference with activity (1)'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:14', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered 'None (0)'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:16', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered 'None (0)'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:19', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered 'No (N)'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-18T23:26:22', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'dc4c60d9-b1cf-48a9-a975-4c4669e7236b' User entered '18 Sep 2020 23:26'	System	19 Sep 2020 03:26:27
	System	19 Sep 2020 03:26:27

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 6'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:23', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered 'None (0)'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1'	System	20 Sep 2020 00:51:06
User entered 'No interference with activity (1)'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:33', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered 'None (0)'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:37', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered 'None (0)'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered 'None (0)'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered 'None (0)'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:50:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered 'No (N)'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-19T20:51:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'fac3e883-f307-478d-b45d-17cbfc025da1' User entered '19 Sep 2020 20:51'	System	20 Sep 2020 00:51:06
	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	14 Sep 2020 17:39:29
User entered 'Day 7'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b' User entered 'None (0)'	System	21 Sep 2020 00:15:20
	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:14:57', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b'	System	21 Sep 2020 00:15:20
User entered 'Some interference with activity (2)'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:15:02', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b'	System	21 Sep 2020 00:15:20
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:15:09', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b'	System	21 Sep 2020 00:15:20
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:15:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b' User entered 'None (0)'	System	21 Sep 2020 00:15:20
	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:15:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b' User entered 'None (0)'	System	21 Sep 2020 00:15:20
	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:15:15', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b' User entered 'No (N)'	System	21 Sep 2020 00:15:20
	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-20T20:15:18', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '89d69d71-5820-41a0-ac57-9975e199b13b' User entered '20 Sep 2020 20:15'	System	21 Sep 2020 00:15:20
	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 17:39:29

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	20 Sep 2020 00:51:06
User entered 'Day 8'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:08:36', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd0888872-92a8-4258-887d-d5d082897fd3'	System	22 Sep 2020 03:08:44
User entered 'Some interference with activity (2)'	System	22 Sep 2020 03:08:44

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:08:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'd0888872-92a8-4258-887d-d5d082897fd3' User entered '21 Sep 2020 23:08'	System	22 Sep 2020 03:08:44
	System	22 Sep 2020 03:08:44

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	21 Sep 2020 00:15:20
User entered 'Day 9'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:02:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c0b5ad69-6bbe-4a77-866c-0a1d227cc3c4'	System	23 Sep 2020 00:02:52
User entered 'Some interference with activity (2)'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:02:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c0b5ad69-6bbe-4a77-866c-0a1d227cc3c4' User entered '22 Sep 2020 20:02'	System	23 Sep 2020 00:02:52
	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	22 Sep 2020 03:08:44
User entered 'Day 10'	System	22 Sep 2020 03:08:44

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-23T22:07:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0d3c3715-9f10-4a4f-8179-d05113a61e5d' User entered 'No interference with activity (1)'	System	24 Sep 2020 02:07:48
	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-23T22:07:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0d3c3715-9f10-4a4f-8179-d05113a61e5d' User entered '23 Sep 2020 22:07'	System	24 Sep 2020 02:07:48
	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 03:08:44

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 03:08:44

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	23 Sep 2020 00:02:52
User entered 'Day 11'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-24T23:40:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '65970962-9719-4f61-a5d3-19bc2baa2f19'	System	25 Sep 2020 03:40:48
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:40:48

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-24T23:40:43', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '65970962-9719-4f61-a5d3-19bc2baa2f19' User entered '24 Sep 2020 23:40'	System	25 Sep 2020 03:40:48
	System	25 Sep 2020 03:40:48

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Sep 2020 02:07:48
User entered 'Day 12'	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-25T21:02:15', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '92719311-e9fa-407e-a3bd-e962dddb01d8' User entered 'None (0)'	System	26 Sep 2020 01:10:37
	System	26 Sep 2020 01:10:37

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:54:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-25T21:02:18', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '92719311-e9fa-407e-a3bd-e962dddb01d8' User entered '25 Sep 2020 21:02'	System	26 Sep 2020 01:10:37
	System	26 Sep 2020 01:10:37

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	21 Sep 2020 00:15:20
User entered 'Day 8'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:08:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '370366b3-f20d-402c-be40-2ac14bdfabe7'	System	22 Sep 2020 03:08:55
User entered 'No interference with activity (1)'	System	22 Sep 2020 03:08:55

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:08:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '370366b3-f20d-402c-be40-2ac14bdfabe7' User entered '21 Sep 2020 23:08'	System	22 Sep 2020 03:08:55
	System	22 Sep 2020 03:08:55

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	21 Sep 2020 00:15:20
User entered 'Day 9'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:02:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '45564cd9-d3ae-44b2-a4ff-6d25f3fb650e' User entered 'None (0)'	System	23 Sep 2020 00:03:06
	System	23 Sep 2020 00:03:06

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:03:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '45564cd9-d3ae-44b2-a4ff-6d25f3fb650e' User entered '22 Sep 2020 20:03'	System	23 Sep 2020 00:03:06
	System	23 Sep 2020 00:03:06

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	21 Sep 2020 00:15:20
User entered 'Day 8'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:08:56', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c873a5fb-b0b5-4694-ac08-d8a3e3bbbb5b' User entered 'No interference with activity (1)'	System	22 Sep 2020 03:09:01
	System	22 Sep 2020 03:09:01

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:08:59', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'c873a5fb-b0b5-4694-ac08-d8a3e3bbbb5b' User entered '21 Sep 2020 23:08'	System	22 Sep 2020 03:09:01
	System	22 Sep 2020 03:09:01

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	21 Sep 2020 00:15:20
User entered 'Day 9'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:03:11', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6897103a-9d7c-4fcd-8ecd-c6d1894e592f' User entered 'None (0)'	System	23 Sep 2020 00:03:25
	System	23 Sep 2020 00:03:25

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:03:22', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6897103a-9d7c-4fcd-8ecd-c6d1894e592f' User entered '22 Sep 2020 20:03'	System	23 Sep 2020 00:03:25
	System	23 Sep 2020 00:03:25

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	20 Sep 2020 00:51:06
User entered 'Day 8'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:09:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a2609b33-923e-4414-a334-a3c1b52ccb49' User entered 'No (N)'	System	22 Sep 2020 03:09:12
	System	22 Sep 2020 03:09:12

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-21T23:09:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a2609b33-923e-4414-a334-a3c1b52ccb49' User entered '21 Sep 2020 23:09'	System	22 Sep 2020 03:09:12
	System	22 Sep 2020 03:09:12

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 00:51:06

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	21 Sep 2020 00:15:20
User entered 'Day 9'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:03:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '45a37df7-0809-4e7d-b883-95a1b3c7d0d8' User entered 'No (N)'	System	23 Sep 2020 00:03:42
	System	23 Sep 2020 00:03:42

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-22T20:03:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '45a37df7-0809-4e7d-b883-95a1b3c7d0d8' User entered '22 Sep 2020 20:03'	System	23 Sep 2020 00:03:42
	System	23 Sep 2020 00:03:42

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 00:15:20

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	23 Sep 2020 00:02:52
User entered 'Day 11'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-24T23:40:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '422891bb-d215-419e-8a35-2695f77f652b' User entered 'No (N)'	System	25 Sep 2020 03:40:54
	System	25 Sep 2020 03:40:54

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-24T23:40:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '422891bb-d215-419e-8a35-2695f77f652b' User entered '24 Sep 2020 23:40'	System	25 Sep 2020 03:40:54
	System	25 Sep 2020 03:40:54

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 00:02:52

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	24 Sep 2020 02:07:48
User entered 'Day 12'	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:54:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-25T21:02:22', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '374571a9-faf1-4cd6-a5d4-2b449ece4726' User entered 'No (N)'	System	26 Sep 2020 01:10:45
	System	26 Sep 2020 01:10:45

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:54:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-09-25T21:02:25', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '374571a9-faf1-4cd6-a5d4-2b449ece4726' User entered '25 Sep 2020 21:02'	System	26 Sep 2020 01:10:45
	System	26 Sep 2020 01:10:45

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:54:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 02:07:48

US3822154

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 10 Jun 2021 09:54:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 02:07:48

US3822154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:36:22

US3822154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered '21 Sep 2020'	Krishna Shah (b) (4)	08 Dec 2020 23:36:22

US3822154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	08 Dec 2020 23:36:22

US3822154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:36:22

US3822154

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:36:27

US3822154

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	08 Dec 2020 23:36:27

US3822154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:36:53

US3822154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered '28 Sep 2020'	Krishna Shah (b) (4)	08 Dec 2020 23:36:53

US3822154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	08 Dec 2020 23:36:53

US3822154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:36:53

US3822154

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:37:01

US3822154

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	08 Dec 2020 23:37:01

US3822154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:37:56

US3822154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered '5 Oct 2020'	Krishna Shah (b) (4)	08 Dec 2020 23:37:56

US3822154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	08 Dec 2020 23:37:56

US3822154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:37:56

US3822154

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:58:48
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:38:01

US3822154

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	08 Dec 2020 23:38:01

US3822154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears there is a "SARS-COV-2 serum" sample with collection date of "28 DEC 2020", under "Unscheduled" Visit in "PPD Central Lab", however in Unscheduled visit assessment, only immunogenicity samples will be collected, Please confirm if the SARS-CoV-2 serum sample dated "28 DEC 2020", has been collected, and if collected please update it under Illness visit folder, as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 09:55:24
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears there is a "SARS-COV-2 serum" sample with collection date of "28 DEC 2020", under "Unscheduled" Visit in "PPD Central Lab", however in Unscheduled visit assessment, only immunogenicity samples will be collected, Please confirm if the SARS-CoV-2 serum sample dated "28 DEC 2020", has been collected, and if collected please update it under Illness visit folder, as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:59:11
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:38:28

US3822154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '16 Oct 2020'	Krishna Shah (b) (4)	08 Dec 2020 23:38:28

US3822154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Clinic (Clinic)'	Krishna Shah (b) (4)	08 Dec 2020 23:38:28

US3822154

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'VISIT3'	System	08 Dec 2020 23:38:28

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '16 Oct 2020'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '12:25'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '16 Oct 2020 12:25'	System	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '98.4' F	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Oral (Oral)'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '80'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'bpm'	System	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '16'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'breaths/min'	System	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '162'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '98'	Krishna Shah (b) (4)	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'mmHg'	System	08 Dec 2020 23:39:14

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55

US3822154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55

US3822154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'No (N)'	Krishna Shah (b) (4)	08 Dec 2020 23:39:25

US3822154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:39:25

US3822154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:39:43

US3822154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '16 Oct 2020'	Krishna Shah (b) (4)	08 Dec 2020 23:39:43

US3822154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered '12:30'	Krishna Shah (b) (4)	08 Dec 2020 23:39:43

US3822154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered '16 Oct 2020 12:30'	System	08 Dec 2020 23:39:43

US3822154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 19:59:02
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:39:50

US3822154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User entered 'I'	System	08 Dec 2020 23:39:50

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 64'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-10-20T18:21:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '463b0ef6-a43f-4097-b462-1b8663d89e1d' User entered 'No (N)'	System	20 Oct 2020 22:21:49
	System	20 Oct 2020 22:21:49

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-10-20T18:21:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '463b0ef6-a43f-4097-b462-1b8663d89e1d'	System	20 Oct 2020 22:21:49
User entered 'No (N)'	System	20 Oct 2020 22:21:49

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-10-20T18:21:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '463b0ef6-a43f-4097-b462-1b8663d89e1d' User entered '20 Oct 2020 18:21:46'	System	20 Oct 2020 22:21:49
	System	20 Oct 2020 22:21:49

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 71'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-10-24T08:25:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0a9ef494-a20d-4b8f-b13c-d965cf1dc8e6'	System	24 Oct 2020 12:25:27
User entered 'No (N)'	System	24 Oct 2020 12:25:27

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-10-24T08:25:20', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0a9ef494-a20d-4b8f-b13c-d965cf1dc8e6'	System	24 Oct 2020 12:25:27
User entered 'No (N)'	System	24 Oct 2020 12:25:27

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-10-24T08:25:25', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '0a9ef494-a20d-4b8f-b13c-d965cf1dc8e6' User entered '24 Oct 2020 08:25:25'	System	24 Oct 2020 12:25:27
	System	24 Oct 2020 12:25:27

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 78'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-02T12:00:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '53ae2a84-e0cb-436c-bc84-330f8d179d35'	System	02 Nov 2020 17:00:20
User entered 'No (N)'	System	02 Nov 2020 17:00:20

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-02T12:00:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '53ae2a84-e0cb-436c-bc84-330f8d179d35'	System	02 Nov 2020 17:00:20
User entered 'No (N)'	System	02 Nov 2020 17:00:20

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-02T12:00:13', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '53ae2a84-e0cb-436c-bc84-330f8d179d35' User entered '02 Nov 2020 12:00:13'	System	02 Nov 2020 17:00:20
	System	02 Nov 2020 17:00:20

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered 'Day 92'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-14T11:53:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8f55a83d-66a1-4c29-b97e-01e7e4d82559' User entered 'No (N)'	System	14 Nov 2020 16:53:56
	System	14 Nov 2020 16:53:56

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-14T11:53:45', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8f55a83d-66a1-4c29-b97e-01e7e4d82559'	System	14 Nov 2020 16:53:56
User entered 'No (N)'	System	14 Nov 2020 16:53:56

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-14T11:53:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '8f55a83d-66a1-4c29-b97e-01e7e4d82559' User entered '14 Nov 2020 11:53:50'	System	14 Nov 2020 16:53:56
	System	14 Nov 2020 16:53:56

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 15:57:06

US3822154

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:12:48
Data entry locked.	System	17 Aug 2020 15:57:06
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 15:57:06

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-27T19:36:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a215f088-12e1-418f-ac67-7ebd26de538b' User entered 'No (N)'	System	28 Nov 2020 00:37:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-27T19:36:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a215f088-12e1-418f-ac67-7ebd26de538b' User entered 'No (N)'	System	28 Nov 2020 00:37:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-11-27T19:37:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'a215f088-12e1-418f-ac67-7ebd26de538b' User entered '27 Nov 2020 19:37:04'	System	28 Nov 2020 00:37:09
	System	28 Nov 2020 00:37:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-02T16:57:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '91b30c07-5d36-4b39-9a55-909888f2e958'	System	02 Dec 2020 21:57:46
User entered 'No (N)'	System	02 Dec 2020 21:57:46

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-02T16:57:38', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '91b30c07-5d36-4b39-9a55-909888f2e958'	System	02 Dec 2020 21:57:46
User entered 'No (N)'	System	02 Dec 2020 21:57:46

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-02T16:57:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '91b30c07-5d36-4b39-9a55-909888f2e958' User entered '02 Dec 2020 16:57:44'	System	02 Dec 2020 21:57:46
	System	02 Dec 2020 21:57:46

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-09T13:17:46', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7eac1ce1-26ad-4c14-a463-b328bfeff1c4'	System	09 Dec 2020 18:17:55
User entered 'No (N)'	System	09 Dec 2020 18:17:55

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-09T13:17:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7eac1ce1-26ad-4c14-a463-b328bfeff1c4' User entered 'No (N)'	System	09 Dec 2020 18:17:55
	System	09 Dec 2020 18:17:55

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-09T13:17:53', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7eac1ce1-26ad-4c14-a463-b328bfeff1c4' User entered '09 Dec 2020 13:17:53'	System	09 Dec 2020 18:17:55
	System	09 Dec 2020 18:17:55

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
User closed query 'Per CDM: Response Noted, Kindly update the Log-line number where the updates has been made. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:09:39
Query 'Per CDM: Response Noted, Kindly update the Log-line number where the updates has been made. Thank you.' answered with 'AEs log line 4 and 5. Conmed log line 34 and 35' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:19:58
User opened query 'Per CDM: Response Noted, Kindly update the Log-line number where the updates has been made. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 10:19:27
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 10:18:17
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AEs and conmeds added' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:31:59
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:38:54

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-16T14:45:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6474160e-7584-4740-9dbf-88b162b1ec37' User entered 'Yes (Y)'	System	16 Dec 2020 19:46:17
	System	16 Dec 2020 19:46:17

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-16T14:45:33', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6474160e-7584-4740-9dbf-88b162b1ec37'	System	16 Dec 2020 19:46:17
User entered 'No (N)'	System	16 Dec 2020 19:46:17

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-16T14:45:40', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6474160e-7584-4740-9dbf-88b162b1ec37'	System	16 Dec 2020 19:46:17
User entered 'No (N)'	System	16 Dec 2020 19:46:17

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-16T14:45:47', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6474160e-7584-4740-9dbf-88b162b1ec37'	System	16 Dec 2020 19:46:17
User entered 'Yes (Y)'	System	16 Dec 2020 19:46:17

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-16T14:46:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6474160e-7584-4740-9dbf-88b162b1ec37'	System	16 Dec 2020 19:46:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 19:46:17

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-16T14:46:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6474160e-7584-4740-9dbf-88b162b1ec37'	System	16 Dec 2020 19:46:17
User entered '16 Dec 2020 14:46:08'	System	16 Dec 2020 19:46:17

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-25T12:43:16', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '560cca8c-99f2-40fd-a1d0-de892614104d' User entered 'Yes (Y)'	System	25 Dec 2020 17:43:58
	System	25 Dec 2020 17:43:58

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-25T12:43:20', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '560cca8c-99f2-40fd-a1d0-de892614104d' User entered 'No (N)'	System	25 Dec 2020 17:43:58
	System	25 Dec 2020 17:43:58

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-25T12:43:26', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '560cca8c-99f2-40fd-a1d0-de892614104d' User entered 'No (N)'	System	25 Dec 2020 17:43:58
	System	25 Dec 2020 17:43:58

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-25T12:43:36', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '560cca8c-99f2-40fd-a1d0-de892614104d'	System	25 Dec 2020 17:43:58
User entered 'Yes (Y)'	System	25 Dec 2020 17:43:58

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-25T12:43:44', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '560cca8c-99f2-40fd-a1d0-de892614104d'	System	25 Dec 2020 17:43:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 17:43:58

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2020-12-25T12:43:49', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '560cca8c-99f2-40fd-a1d0-de892614104d' User entered '25 Dec 2020 12:43:49'	System	25 Dec 2020 17:43:58
	System	25 Dec 2020 17:43:58

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-02T16:16:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4c205a1d-9990-4f7b-a4ca-ced08d76acec' User entered 'Yes (Y)'	System	02 Jan 2021 21:17:41
	System	02 Jan 2021 21:17:41

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-02T16:17:06', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4c205a1d-9990-4f7b-a4ca-ced08d76acec'	System	02 Jan 2021 21:17:41
User entered 'No (N)'	System	02 Jan 2021 21:17:41

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-02T16:17:12', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4c205a1d-9990-4f7b-a4ca-ced08d76acec' User entered 'No (N)'	System	02 Jan 2021 21:17:41
	System	02 Jan 2021 21:17:41

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-02T16:17:21', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4c205a1d-9990-4f7b-a4ca-ced08d76acec' User entered 'Yes (Y)'	System	02 Jan 2021 21:17:41
	System	02 Jan 2021 21:17:41

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-02T16:17:25', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4c205a1d-9990-4f7b-a4ca-ced08d76acec'	System	02 Jan 2021 21:17:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 21:17:41

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-02T16:17:32', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '4c205a1d-9990-4f7b-a4ca-ced08d76acec' User entered '02 Jan 2021 16:17:32'	System	02 Jan 2021 21:17:41
	System	02 Jan 2021 21:17:41

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-16T13:31:35', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '402bac92-8773-445c-980a-90f579a97ab2' User entered 'No (N)'	System	16 Jan 2021 18:31:45
	System	16 Jan 2021 18:31:45

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-16T13:31:37', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '402bac92-8773-445c-980a-90f579a97ab2'	System	16 Jan 2021 18:31:45
User entered 'No (N)'	System	16 Jan 2021 18:31:45

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-16T13:31:41', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '402bac92-8773-445c-980a-90f579a97ab2' User entered '16 Jan 2021 13:31:41'	System	16 Jan 2021 18:31:45
	System	16 Jan 2021 18:31:45

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-20T00:03:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7bc27f90-36e8-4e91-bf9b-99375db11234'	System	29 Jan 2021 17:02:50
User entered 'No (N)'	System	29 Jan 2021 17:02:50

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-20T00:03:07', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7bc27f90-36e8-4e91-bf9b-99375db11234' User entered 'No (N)'	System	29 Jan 2021 17:02:50
	System	29 Jan 2021 17:02:50

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-20T00:03:10', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '7bc27f90-36e8-4e91-bf9b-99375db11234' User entered '20 Jan 2021 00:03:10'	System	29 Jan 2021 17:02:50
	System	29 Jan 2021 17:02:50

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-29T12:01:01', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1650f0aa-cedb-45d3-845f-151c0b3dc3f7'	System	29 Jan 2021 17:03:30
User entered 'No (N)'	System	29 Jan 2021 17:03:30

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-29T12:01:04', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1650f0aa-cedb-45d3-845f-151c0b3dc3f7'	System	29 Jan 2021 17:03:30
User entered 'No (N)'	System	29 Jan 2021 17:03:30

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-01-29T12:01:08', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '1650f0aa-cedb-45d3-845f-151c0b3dc3f7' User entered '29 Jan 2021 12:01:08'	System	29 Jan 2021 17:03:30
	System	29 Jan 2021 17:03:30

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-06T19:55:50', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '10b9d23e-eac9-4f6f-99e6-bec811962fc2' User entered 'No (N)'	System	07 Feb 2021 00:56:02
	System	07 Feb 2021 00:56:02

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-06T19:55:54', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '10b9d23e-eac9-4f6f-99e6-bec811962fc2'	System	07 Feb 2021 00:56:02
User entered 'No (N)'	System	07 Feb 2021 00:56:02

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-06T19:55:58', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '10b9d23e-eac9-4f6f-99e6-bec811962fc2' User entered '06 Feb 2021 19:55:58'	System	07 Feb 2021 00:56:02
	System	07 Feb 2021 00:56:02

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-10T10:01:27', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f15b2a14-5365-4ce4-8bb5-fd6bd0a31e48' User entered 'No (N)'	System	17 Feb 2021 05:03:14

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-10T10:01:30', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f15b2a14-5365-4ce4-8bb5-fd6bd0a31e48' User entered 'No (N)'	System	17 Feb 2021 05:03:14
	System	17 Feb 2021 05:03:14

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-10T10:01:34', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'f15b2a14-5365-4ce4-8bb5-fd6bd0a31e48' User entered '10 Feb 2021 10:01:34'	System	17 Feb 2021 05:03:14
	System	17 Feb 2021 05:03:14

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-17T00:01:48', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6f4876ee-d87f-4800-8804-30bf8a8f88b8' User entered 'No (N)'	System	17 Feb 2021 05:03:51
	System	17 Feb 2021 05:03:51

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-17T00:01:51', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6f4876ee-d87f-4800-8804-30bf8a8f88b8'	System	17 Feb 2021 05:03:51
User entered 'No (N)'	System	17 Feb 2021 05:03:51

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-17T00:01:54', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '6f4876ee-d87f-4800-8804-30bf8a8f88b8' User entered '17 Feb 2021 00:01:54'	System	17 Feb 2021 05:03:51
	System	17 Feb 2021 05:03:51

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-26T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '14cf21a8-ad5c-4879-a8f0-154afd360e77'	System	26 Feb 2021 17:02:28
User entered 'No (N)'	System	26 Feb 2021 17:02:28

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-26T12:00:34-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '14cf21a8-ad5c-4879-a8f0-154afd360e77'	System	26 Feb 2021 17:02:28
User entered 'No (N)'	System	26 Feb 2021 17:02:28

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-02-26T12:00:41-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '14cf21a8-ad5c-4879-a8f0-154afd360e77'	System	26 Feb 2021 17:02:28
User entered '26 Feb 2021 17:00:41'	System	26 Feb 2021 17:02:28

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-03T07:28:39-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5dc9ecc8-6c3e-4dd9-96b9-fd43ee7fa5ff'	System	03 Mar 2021 12:28:53
User entered 'No (N)'	System	03 Mar 2021 12:28:53

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-03T07:28:43-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5dc9ecc8-6c3e-4dd9-96b9-fd43ee7fa5ff'	System	03 Mar 2021 12:28:53
User entered 'No (N)'	System	03 Mar 2021 12:28:53

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-03T07:28:51-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '5dc9ecc8-6c3e-4dd9-96b9-fd43ee7fa5ff' User entered '03 Mar 2021 07:28:51'	System	03 Mar 2021 12:28:53
	System	03 Mar 2021 12:28:53

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-10T08:08:42-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '35c652b1-5b44-4744-a0c8-db7d53bc658d'	System	10 Mar 2021 13:08:53
User entered 'No (N)'	System	10 Mar 2021 13:08:53

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-10T08:08:45-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '35c652b1-5b44-4744-a0c8-db7d53bc658d'	System	10 Mar 2021 13:08:53
User entered 'No (N)'	System	10 Mar 2021 13:08:53

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-10T08:08:50-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '35c652b1-5b44-4744-a0c8-db7d53bc658d' User entered '10 Mar 2021 08:08:50'	System	10 Mar 2021 13:08:53
	System	10 Mar 2021 13:08:53

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-20T18:03:33-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '79ca6b97-9530-4b5b-be9b-e22cf7403627'	System	20 Mar 2021 22:07:05
User entered 'No (N)'	System	20 Mar 2021 22:07:05

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-20T18:03:37-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '79ca6b97-9530-4b5b-be9b-e22cf7403627'	System	20 Mar 2021 22:07:05
User entered 'No (N)'	System	20 Mar 2021 22:07:05

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-20T18:03:42-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '79ca6b97-9530-4b5b-be9b-e22cf7403627' User entered '20 Mar 2021 18:03:42'	System	20 Mar 2021 22:07:05
	System	20 Mar 2021 22:07:05

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-25T13:51:44-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '07e83935-8b40-4e09-8a21-8e45af077f6a' User entered 'Yes (Y)'	System	25 Mar 2021 17:52:24
	System	25 Mar 2021 17:52:24

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-25T13:51:47-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '07e83935-8b40-4e09-8a21-8e45af077f6a'	System	25 Mar 2021 17:52:24
User entered 'No (N)'	System	25 Mar 2021 17:52:24

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-25T13:51:51-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '07e83935-8b40-4e09-8a21-8e45af077f6a' User entered 'No (N)'	System	25 Mar 2021 17:52:24
	System	25 Mar 2021 17:52:24

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-25T13:52:14-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '07e83935-8b40-4e09-8a21-8e45af077f6a' User entered 'No (N)'	System	25 Mar 2021 17:52:24
	System	25 Mar 2021 17:52:24

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-25T13:52:18-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '07e83935-8b40-4e09-8a21-8e45af077f6a' User entered '25 Mar 2021 13:52:18'	System	25 Mar 2021 17:52:24
	System	25 Mar 2021 17:52:24

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-02T12:03:25-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '98672c6a-bc0d-43d5-aa93-e395a5b52bb1' User entered 'No (N)'	System	02 Apr 2021 16:08:59
	System	02 Apr 2021 16:08:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-02T12:03:31-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '98672c6a-bc0d-43d5-aa93-e395a5b52bb1' User entered 'No (N)'	System	02 Apr 2021 16:08:59
	System	02 Apr 2021 16:08:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-02T12:03:36-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '98672c6a-bc0d-43d5-aa93-e395a5b52bb1' User entered '02 Apr 2021 12:03:36'	System	02 Apr 2021 16:08:59
	System	02 Apr 2021 16:08:59

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-07T18:05:28-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'edd1bd17-01d8-4dc6-9c51-fa51005338db' User entered 'No (N)'	System	07 Apr 2021 22:10:52
	System	07 Apr 2021 22:10:52

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-07T18:05:33-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'edd1bd17-01d8-4dc6-9c51-fa51005338db' User entered 'No (N)'	System	07 Apr 2021 22:10:52

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-07T18:05:37-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'edd1bd17-01d8-4dc6-9c51-fa51005338db' User entered '07 Apr 2021 18:05:37'	System	07 Apr 2021 22:10:52
	System	07 Apr 2021 22:10:52

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-17T18:24:20-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '9fad74ae-52eb-4eff-85a4-62a590c09ef2'	System	17 Apr 2021 22:24:29
User entered 'No (N)'	System	17 Apr 2021 22:24:29

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-17T18:24:23-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '9fad74ae-52eb-4eff-85a4-62a590c09ef2'	System	17 Apr 2021 22:24:29
User entered 'No (N)'	System	17 Apr 2021 22:24:29

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-17T18:24:27-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '9fad74ae-52eb-4eff-85a4-62a590c09ef2'	System	17 Apr 2021 22:24:29
User entered '17 Apr 2021 18:24:27'	System	17 Apr 2021 22:24:29

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-23T12:21:51-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '62251494-2330-4e74-b6da-69c88abcf547'	System	23 Apr 2021 16:22:07
User entered 'No (N)'	System	23 Apr 2021 16:22:07

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-23T12:21:54-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '62251494-2330-4e74-b6da-69c88abcf547'	System	23 Apr 2021 16:22:07
User entered 'No (N)'	System	23 Apr 2021 16:22:07

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-04-23T12:22:04-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '62251494-2330-4e74-b6da-69c88abcf547'	System	23 Apr 2021 16:22:07
User entered '23 Apr 2021 12:22:04'	System	23 Apr 2021 16:22:07

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-05-01T20:04:04-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2ea68081-e921-4703-8b51-aafcb8e08baf'	System	02 May 2021 00:04:18
User entered 'No (N)'	System	02 May 2021 00:04:18

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-05-01T20:04:09-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2ea68081-e921-4703-8b51-aafcb8e08baf'	System	02 May 2021 00:04:18
User entered 'No (N)'	System	02 May 2021 00:04:18

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-05-01T20:04:15-04:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: '2ea68081-e921-4703-8b51-aafcb8e08baf'	System	02 May 2021 00:04:18
User entered '01 May 2021 20:04:15'	System	02 May 2021 00:04:18

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:12:09

US3822154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:12:09
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:12:09

US3822154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:54:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:32:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-03T07:29:09-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ea355e37-6708-4719-86e6-966e9389c202'	System	03 Mar 2021 12:29:40
User entered 'Yes (Y)'	System	03 Mar 2021 12:29:40

US3822154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:54:53

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:32:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-03T07:29:21-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ea355e37-6708-4719-86e6-966e9389c202'	System	03 Mar 2021 12:29:40
User entered 'Yes (Y)'	System	03 Mar 2021 12:29:40

US3822154

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:54:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:32:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1E88052E-64E0-4044-8791-9F354F176D09)', Time: '2021-03-03T07:29:30-05:00', User OID: 'PatientReportedOutcome (US3822154)', ODM File OID: 'ea355e37-6708-4719-86e6-966e9389c202' User entered '03 Mar 2021 07:29:30'	System	03 Mar 2021 12:29:40
	System	03 Mar 2021 12:29:40

US3822154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:12:55
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 28-DEC-2020 is reported under Unscheduled visit in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if Yes, then please confirm the correct visit as there is no provision to record Unscheduled visit for this sample and update accordingly for the corresponding date (28DEC2020). Else clarify, Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 09:55:44
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 28-DEC-2020 is reported under Unscheduled visit in PPD portal; however, data is missing in EDC. Kindly review if the swab sample was collected, if Yes, then please confirm the correct visit as there is no provision to record Unscheduled visit for this sample and update accordingly for the corresponding date (28DEC2020). Else clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 08:26:34
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:40:20

US3822154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:12:55
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears there is a "SARS-COV-2 serum" sample with collection date of "28 DEC 2020", under "Unscheduled" Visit in "PPD Central Lab", however in Unscheduled visit assessment, only immunogenicity samples will be collected, Please confirm if the SARS-CoV-2 serum sample dated "23 OCT 2020", has been collected, and if collected please update it under Illness visit folder, as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:58:13
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears there is a "SARS-COV-2 serum" sample with collection date of "28 DEC 2020", under "Unscheduled" Visit in "PPD Central Lab", however in Unscheduled visit assessment, only immunogenicity samples will be collected, Please confirm if the SARS-CoV-2 serum sample dated "23 OCT 2020", has been collected, and if collected please update it under Illness visit folder, as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:57:55
User entered '9 Nov 2020'	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:40:20

US3822154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:12:55
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	08 Dec 2020 23:40:20

US3822154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:12:55
User entered empty.	Krishna Shah (b) (4)	08 Dec 2020 23:40:20

US3822154

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:12:55
User entered 'Yes (Y)'	Krishna Shah (b) (4)	08 Dec 2020 23:40:30

US3822154

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:19:55
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 is reported under Unscheduled visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:05:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 is reported under Unscheduled visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 09:50:37
User entered 'I'	System	08 Dec 2020 23:40:30

US3822154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	11 Jan 2021 22:20:13

US3822154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered '14 Dec 2020'	Kelly Woodell (b) (4)	11 Jan 2021 22:20:13

US3822154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	11 Jan 2021 22:20:13

US3822154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	Kelly Woodell (b) (4)	11 Jan 2021 22:20:13

US3822154

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	11 Jan 2021 22:20:17

US3822154

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered 'I'	System	11 Jan 2021 22:20:17

US3822154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:46:57

US3822154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:46:57

US3822154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:46:57

US3822154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:46:57

US3822154

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 20:47:00

US3822154

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered 'I'	System	13 Jan 2021 20:47:00

US3822154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:38:39

US3822154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:38:39

US3822154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:38:39

US3822154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:38:39

US3822154

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 21:38:42

US3822154

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered 'I'	System	15 Feb 2021 21:38:42

US3822154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:36:51

US3822154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:36:51

US3822154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[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 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:36:51

US3822154

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered 'VISIT4'	System	15 Mar 2021 17:36:51

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered empty.	System	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered empty.	System	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered empty.	System	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered empty.	System	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered empty.	System	01 Apr 2021 15:43:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57

US3822154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:37:07

US3822154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:37:07

US3822154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:37:28

US3822154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:37:28

US3822154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered '13:21'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:37:28

US3822154

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered '15 Mar 2021 13:21'	System	15 Mar 2021 17:37:28

US3822154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 17:37:31

US3822154

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:57:57
User entered 'I'	System	15 Mar 2021 17:37:31

US3822154

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:53:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:20:58

US3822154

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:53:38
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:20:58

US3822154

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:53:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:20:58

US3822154

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:53:38
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:20:58

US3822154

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:53:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:20:50

US3822154

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 11:20:50

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:54:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '28 Dec 2020'	Kelly Woodell (b) (4)	12 Jan 2021 14:24:12

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:54:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '10:48'	Kelly Woodell (b) (4)	12 Jan 2021 14:24:12

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:54:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:54
User entered '28 Dec 2020 10:48'	System	12 Jan 2021 14:24:12

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:54:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Safety Call (Safety Call)'	Kelly Woodell (b) (4)	12 Jan 2021 14:24:12

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:54:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:10:54
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	12 Jan 2021 14:24:12

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 14:25:50
User entered '29 Dec 2020' reason for change: Data Entry Error	System	12 Jan 2021 14:25:50
User opened query 'Data is required. Please complete.' (Site from System).	Kelly Woodell (b) (4)	12 Jan 2021 14:25:50
User entered empty.	(b) (4)	
	System	12 Jan 2021 14:25:43
	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43
	(b) (4)	

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'I'	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User entered empty.	System	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:54:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 14:25:43

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-Query: Response noted, however there is no initiated Illness visit folder with corresponding SARS-CoV-2 sample dated 28 DEC 2020. As explained in the above query, please note that EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder, under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to create Illness visit folder and update the data in SARS sample collection forms accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 17:11:24
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:19:15
Query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-Query: Response noted, however there is no initiated Illness visit folder with corresponding SARS-CoV-2 sample dated 28 DEC 2020. As explained in the above query, please note that EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder, under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to create Illness visit folder and update the data in SARS sample collection forms accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:15:39
User opened query 'Per GCL Lab Recon: SARS-CoV-2 sample: Re-Query: Response noted, however there is no initiated Illness visit folder with corresponding SARS-CoV-2 sample dated 28 DEC 2020. As explained in the above query, please note that EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder, under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to create Illness visit folder and update the data in SARS sample collection forms accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 13:50:20

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 28 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC, by creating an Illness visit folder as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 13:50:20
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 28 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC, by creating an Illness visit folder as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' answered with 'Data in edc already' (Site from DM).	Kelly Woodell (b) (4)	14 Jan 2021 15:36:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 28 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC, by creating an Illness visit folder as EDC has provision to update the SARS-COV-2 sample data only in Illness visit folder(Illness Visit/convalescence visit day 28), under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form only, hence we need to update the data in those forms accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:58:28
User entered '28 Dec 2020'	Kelly Woodell (b) (4)	12 Jan 2021 14:26:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

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 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample dated 28DEC2020 is present in PPD central lab, please review the preclaus and update the correct sample details to correct subject ID and visit in PPD portal, confirm the correct sample details, subject ID and visit in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 07:58:52
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:19:15
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample dated 28DEC2020 is present in PPD central lab, please review the preclaus and update the correct sample details to correct subject ID and visit in PPD portal, confirm the correct sample details, subject ID and visit in query response.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:15:52
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, sample dated 28DEC2020 is present in PPD central lab, please review the preclaus and update the correct sample details to correct subject ID and visit in PPD portal, confirm the correct sample details, subject ID and visit in query response.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:17:14
User closed query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 28DEC2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 28DEC2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:17:14

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 28DEC2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 28DEC2020 for this subject then update the Preclarus. Thank you. ' answered with 'Per source nasal swab was collected' (Site from DM).	Kelly Woodell (b) (4)	14 Jan 2021 15:38:02
User opened query 'Per GCL LAB reconciliation: Saliva: PPD lab has a 28DEC2020 Saliva sample reported. Please confirm if the Saliva sample was also collected along with the Swab sample at this COVID-19 Assessment visit then as per CCG v 4.0 pg 28, the Saliva details will be recorded in a same date 2nd COVID-19 visit with Saliva details in COVID Diagnostic form. Or if Saliva sample was not collected on 28DEC2020 for this subject then update the Preclarus. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:27:14
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[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 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:15
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query ' Per GCL Lab Reconciliation: Nasopharyngeal Swab: Requery: Per response noted, however, since the sample dated 28DEC2020 is present in Unscheduled Visit in PPD Central Lab, please confirm the Correct Visit for this sample. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:25:04
Query ' Per GCL Lab Reconciliation: Nasopharyngeal Swab: Requery: Per response noted, however, since the sample dated 28DEC2020 is present in Unscheduled Visit in PPD Central Lab, please confirm the Correct Visit for this sample. Thank you.' answered with 'Per source, on 28DEC2020, patient had an initial illness visit. Unscheduled kit might have been used due to a lab kit shortage. 28DEC2020 was an illness visit, not unscheduled. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:38:57
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:19:15
User opened query ' Per GCL Lab Reconciliation: Nasopharyngeal Swab: Requery: Per response noted, however, since the sample dated 28DEC2020 is present in Unscheduled Visit in PPD Central Lab, please confirm the Correct Visit for this sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:02:20
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Swab Sample with date 28Dec2020 labelled as "Unscheduled". Please confirm the correct visit name and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:02:20
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Swab Sample with date 28Dec2020 labelled as "Unscheduled". Please confirm the correct visit name and reconcile. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:15:55

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Swab Sample with date 28Dec2020 labelled as "Unscheduled". Please confirm the correct visit name and reconcile. Thank you.' (Site from DM). User entered '28 Dec 2020'	(b) (4), (b) (6)	15 Jan 2021 12:25:22
	Kelly Woodell (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:15
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:15
User entered empty.	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[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 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:15
User entered 'No (N)'	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:15
User entered empty.	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:19:15
User entered empty.	Kelly Woodell (b) (4) (b) (4)	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:54:53

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:07
User entered '0'	System	12 Jan 2021 14:26:45

US3822154

Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:54:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:16
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	Kelly Woodell (b) (4)	26 Jan 2021 16:26:38

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:54:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:54:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:46:04
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:44

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:32
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:16:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 19:08:08

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 28DEC2020 is present in Preclarus report, hence if sample not collected for this subject then please confirm the correct subject ID and visit in query response and also update the Preclarus.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	07 Apr 2021 09:54:27 02 Apr 2021 21:06:51
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 28DEC2020 is present in Preclarus report, hence if sample not collected for this subject then please confirm the correct subject ID and visit in query response and also update the Preclarus.' answered with 'Subject ID has been confirmed in Preclarus. Sample was never collected. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:49:01
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 28DEC2020 is present in Preclarus report, hence if sample not collected for this subject then please confirm the correct subject ID and visit in query response and also update the Preclarus.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:04:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 28DEC2020 with Accession number 1F600382002 is reported under Illness D1 [2] visit in Preclarus portal, please review and update the correct visit. If the sample has been collected for Unscheduled saliva then per CCG Version 5.0 Page # 58 please initiate COVID 19 Assessment visit with same date and add the Saliva data in the COVID Diagnostic form in EDC, if no sample collected on this day then please update the preclaus data to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:04:49
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:16:36

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 28DEC2020 with Accession number 1F600382002 is reported under Illness D1 [2] visit in Preclarus portal, please review and update the correct visit. If the sample has been collected for Unscheduled saliva then per CCG Version 5.0 Page # 58 please initiate COVID 19 Assessment visit with same date and add the Saliva data in the COVID Diagnostic form in EDC, if no sample collected on this day then please update the preclaus data to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' answered with 'Sample was never collected.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:49:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Sample dated 28DEC2020 with Accession number 1F600382002 is reported under Illness D1 [2] visit in Preclarus portal, please review and update the correct visit. If the sample has been collected for Unscheduled saliva then per CCG Version 5.0 Page # 58 please initiate COVID 19 Assessment visit with same date and add the Saliva data in the COVID Diagnostic form in EDC, if no sample collected on this day then please update the preclaus data to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:22:11
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 with Accession number 1F600382002 is reported under Illness Visit day 1 in Preclarus portal, please review and update the correct visit to reflect correct with EDC data, if no sample collected on this day then update the sample details in preclarus to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:22:11

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 with Accession number 1F600382002 is reported under Illness Visit day 1 in Preclarus portal, please review and update the correct visit to reflect correct with EDC data, if no sample collected on this day then update the sample details in preclarus to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' answered with 'Date is recorded in EDC as 12/28/20' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	18 Mar 2021 16:59:20
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28DEC2020 with Accession number 1F600382002 is reported under Illness Visit day 1 in Preclarus portal, please review and update the correct visit to reflect correct with EDC data, if no sample collected on this day then update the sample details in preclarus to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 07:24:00
User entered '28 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 19:08:08

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:32
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:16:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Jan 2021 19:08:08

US3822154

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:32
User entered 'SICKD1'	System	26 Jan 2021 19:08:08

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:27:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:27:22
User entered '28 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:27:24
User entered '16:05'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User entered '28 Dec 2020 16:05'	System	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 17:11:51
User closed query 'Unable to locate in CRIO.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:02:30
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:02:17
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Data is required. Please provide.' answered with 'not collected' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:21
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:50:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:50:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:50:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:50:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:50:01
User entered 'NC' (non-conformant).	(b) (4), (b) (6)	30 Mar 2021 19:50:01
Query 'Unable to locate in CRIO.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:47:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:46:49
User entered '0' (non-conformant).	(b) (4), (b) (6)	30 Mar 2021 19:46:49
User opened query 'Unable to locate in CRIO.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:27:44
User entered '70' in	(b) (4), (b) (6)	26 Jan 2021 19:10:10
DataPoint set to visible.	System	26 Jan 2021 19:08:08

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 17:11:53
User closed query 'Unable to locate in CRIO.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:02:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:02:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Data is required. Please provide.' answered with 'not collected' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:27
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:50:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:50:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:50:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:50:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:50:01
User entered 'NC' (non-conformant).	(b) (4), (b) (6)	30 Mar 2021 19:50:01
Query 'Unable to locate in CRIO.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:48:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Mar 2021 19:46:49
User entered '0' (non-conformant).	(b) (4), (b) (6)	30 Mar 2021 19:46:49
User opened query 'Unable to locate in CRIO.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:28:03
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 19:27:48
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:27:46

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '177.8' lb	(b) (4), (b) (6)	26 Jan 2021 19:10:10
DataPoint set to visible.	System	26 Jan 2021 19:08:08

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:28:56
User closed query 'Temperature is 98.6 in CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:28:44
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Temperature is 98.6 in CRIO. Please reconcile and update where applicable.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:48:18
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:46:49
User opened query 'Temperature is 98.6 in CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:19:13
User entered '98.5' F	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:28:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:28:25
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:29:26
User closed query 'Heart Rate is recorded as 119 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:29:12
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Heart Rate is recorded as 119 per CRIO. Please reconcile and update where applicable.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:48:31
User entered '119' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:47:34
User opened query 'Heart Rate is recorded as 119 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:25:00
User entered '80'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User entered 'bpm'	System	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:30:03
User closed query 'Respiratory Rate is recorded as 26 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:29:47
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Respiratory Rate is recorded as 26 per CRIO. Please reconcile and update where applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:48:45
User entered '26' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:47:34
User opened query 'Respiratory Rate is recorded as 26 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:26:47
Query 'Respiratory Rate is recorded as 26 per CRIO. Please reconcile and update where applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:25:57
User opened query 'Respiratory Rate is recorded as 26 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:25:50
User entered '16'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User entered 'breaths/min'	System	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:30:36
User closed query 'Systolic BP is recorded as 158 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:30:24
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Systolic BP is recorded as 158 per CRIO. Please reconcile and update where applicable.' answered with 'updated' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:49:00
User entered '158' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:47:34
User opened query 'Systolic BP is recorded as 158 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:29:23
User entered '154'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User entered 'mmHg'	System	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:11:58
User closed query 'Diastolic BP is recorded as 110 per CRIO. Please reconcile and update where applicable.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	06 Apr 2021 16:31:01 06 Apr 2021 16:30:48
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:50:32
Query 'Diastolic BP is recorded as 110 per CRIO. Please reconcile and update where applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:49:22
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Mar 2021 19:47:34
User entered '110' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:47:34
User opened query 'Diastolic BP is recorded as 110 per CRIO. Please reconcile and update where applicable.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:30:19
User entered '84'	(b) (4), (b) (6)	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41
User entered 'mmHg'	System	26 Jan 2021 19:10:10

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41

US3822154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:41

US3822154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:47
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:10:49

US3822154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:47
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:10:49

US3822154

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:54:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:11:02

US3822154

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:45:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:11:02

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:05

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:05

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:05

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	26 Jan 2021 19:16:05

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 19:16:14

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:17

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:17

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:54:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:22

US3822154

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:54:53

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:16:22

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 13:56:45

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 13:56:45

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Jan 2021 13:56:45

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 13:56:45

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:03:29
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:15:17
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:53:58

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User closed query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 19:16:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:03:29
	(b) (4)	
Query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:15:35
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 20:15:17
User opened query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:29:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:53:58

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:38:30
	(b) (4)	
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	21 Apr 2021 11:06:29
User closed query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:06:27
Query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' answered with 'updated per IRT unblinding date' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:34:24
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Patient unblinded in IRT prior to coming into clinic to actually be unblinded' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 14:33:50
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	16 Apr 2021 14:33:43
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 14:33:43
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:33:43
User opened query 'Per CDM RQ: Response noted. However, this field is the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:23:35
User closed query 'Per CDM : Per IRT : subject was unblinded on 14JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:23:35
Query 'Per CDM : Per IRT : subject was unblinded on 14JAN2021. Please review and reconcile.' answered with 'Subject unblinding in IRT done on 14JAN2021 but SUBJECT was actually unblinded in clinic 15JAN2021.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:16:04

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Per CDM : Per IRT : subject was unblinded on 14JAN2021. Please review and reconcile. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Christina Kennelly (b) (4)	08 Apr 2021 14:00:53 02 Apr 2021 21:06:51
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'I'	System	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:54:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'I'	System	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '70' in	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '206.2' lb	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '29.64848'	System	20 Jan 2021 14:13:07
DataPoint set to visible.	System	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '70' in	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '206.2' lb	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '29.64848'	System	20 Jan 2021 14:13:07
DataPoint set to visible.	System	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '14:17'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Jan 2021 14:17'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '99.1' F	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '78'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'bpm'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '20'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'breaths/min'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '158'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '99'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '70' in	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '206.2' lb	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '29.64848'	System	20 Jan 2021 14:13:07
DataPoint set to visible.	System	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15:34'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Jan 2021 15:34'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '97.6' F	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '72'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'bpm'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'breaths/min'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '160'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '102'	(b) (4), (b) (6)	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	20 Jan 2021 14:13:07

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:13:40

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:13:40

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mRNA-1273'	System	20 Jan 2021 14:15:41
DataPoint set to visible.	System	20 Jan 2021 13:57:15

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '14:55'	(b) (4), (b) (6)	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Jan 2021 14:55'	System	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'ONCE'	System	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 14:15:41

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 13:57:32

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 13:57:32

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '14:25'	(b) (4), (b) (6)	20 Jan 2021 13:57:32

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Jan 2021 14:25'	System	20 Jan 2021 13:57:32

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 13:57:52

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 13:57:52

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:54:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '14:35'	(b) (4), (b) (6)	20 Jan 2021 13:57:52

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:54:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Jan 2021 14:35'	System	20 Jan 2021 13:57:52

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 13:58:09

US3822154

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'I'	System	20 Jan 2021 13:58:09

US3822154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:41:11

US3822154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered '22 Jan 2021'	(b) (4), (b) (6)	15 Feb 2021 19:41:11

US3822154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Feb 2021 19:41:11

US3822154

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 19:41:11

US3822154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:41:14

US3822154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'I'	System	15 Feb 2021 19:41:14

US3822154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'I'	System	15 Feb 2021 19:41:14
DataPoint set to visible.	System	15 Feb 2021 19:41:14

US3822154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:41:30

US3822154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 19:41:30

US3822154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Feb 2021 19:41:30

US3822154

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'OLD29'	System	15 Feb 2021 19:41:30

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '11:10'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Feb 2021 11:10'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '98.0' F	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '64'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'bpm'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'breaths/min'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '128'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '12:17'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Feb 2021 12:17'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 07:33:12
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PI, NCS' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 15:45:21
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Feb 2021 19:44:13
User entered '96.6' F	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '68'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'bpm'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'breaths/min'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '148'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '104'	(b) (4), (b) (6)	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mmHg'	System	15 Feb 2021 19:44:13

US3822154

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 19:49:30

US3822154

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 19:49:30

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'mRNA-1273'	System	15 Feb 2021 19:49:58
DataPoint set to visible.	System	15 Feb 2021 19:41:14

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '11:47' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 19:50:29
User entered '14:14'	(b) (4), (b) (6)	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Feb 2021 11:47'	System	15 Feb 2021 19:50:29
User entered '15 Feb 2021 14:14'	System	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 19:50:48
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'ONCE'	System	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 19:49:58

US3822154

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 19:50:51

US3822154

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'I'	System	15 Feb 2021 19:50:51

US3822154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 20:36:07

US3822154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered '23 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 20:36:07

US3822154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Feb 2021 20:36:07

US3822154

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 20:36:07

US3822154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:37:48
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 06:44:33
	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered with 'Data entered in error' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 16:39:14
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 21:38:20
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 21:38:20
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Feb 2021 21:38:12
	(b) (4), (b) (6)	

US3822154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '1'	System	15 Mar 2021 17:37:48
User entered empty.	System	15 Feb 2021 21:38:20
User entered '1'	System	15 Feb 2021 21:38:12

US3822154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:37:59

US3822154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 17:37:59

US3822154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Mar 2021 17:37:59

US3822154

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered 'OLD57'	System	15 Mar 2021 17:37:59

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered empty.	System	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered empty.	System	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered empty.	System	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered empty.	System	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered empty.	System	15 Mar 2021 17:38:03

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20

US3822154

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20

US3822154

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Mar 2021 17:38:22

US3822154

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 17:38:22

US3822154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Mar 2021 17:38:33

US3822154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '15 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 17:38:33

US3822154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered '13:21'	(b) (4), (b) (6)	15 Mar 2021 17:38:33

US3822154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:53:20
User entered '15 Mar 2021 13:21'	System	15 Mar 2021 17:38:33

US3822154

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:54:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:53
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (DAY 8 on 21SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:04:43
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE and JOINT ACHES persist beyond Day 7 (Day 8 on 24AUG2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:04:38
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (DAY 8 on 21SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Per patient phone call (day 36) patient reported 14SEP-16SEP. This did not last more than 7days. Please see CRIO for this information. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:39:07
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE and JOINT ACHES persist beyond Day 7 (Day 8 on 24AUG2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'Fatigue has already been added as a solicited AE. Patient reported it started on 17AUG-25AUG. This has been reported in CRIO and EDC as solicited because it started the day of vaccination. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:32:34

US3822154

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:54:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (DAY 8 on 21SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 08:44:18
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE and JOINT ACHES persist beyond Day 7 (Day 8 on 24AUG2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 08:44:13
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:04:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:28:26

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:31:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:31:17
Data point term sent to Coder	System	15 Oct 2020 00:30:20
User entered 'Fatigue'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 00:29:44
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:29:44
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 00:29:24
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User entered '14 Sep 2020 00:00'	System	15 Oct 2020 00:29:44
User entered empty.	System	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '25 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	08 Dec 2020 23:50:53
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 00:29:44
User entered '23:59' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 00:29:44
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 00:29:24
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User entered '25 Sep 2020 23:59'	System	08 Dec 2020 23:50:53
User entered '21 Sep 2020 23:59'	System	15 Oct 2020 00:29:44
User entered empty.	System	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'l'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Oct 2020 00:29:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User entered '0'	System	15 Oct 2020 00:29:24

US3822154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16
User entered '0'	System	15 Oct 2020 00:29:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:17
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:52:24
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Patient was not assessed for COVID since this was an injection reaction' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:29:23
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:27:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site joint pain, LLT: Injection site joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Feb 2021 21:03:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Feb 2021 21:03:00
Data point term sent to Coder	System	11 Feb 2021 16:28:20
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 16:28:12
User entered 'INJECTION SITE ARTHRALGIA IN MULTIPLE JOINTS' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 16:28:12
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of ARTHRALGIA. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 10:51:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia multiple - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 11:10:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[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)	28 Jan 2021 11:10:16
Data point term sent to Coder	(b) (4)	27 Jan 2021 18:36:42
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of ARTHRALGIA. Please reconcile with the ConMed eCRF so there is an appropriate match.	System	27 Jan 2021 18:36:42
' answered with 'UPDATED. Per source it was several joints' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:36:42
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 18:36:03
Coding entries removed.	(b) (4), (b) (6)	27 Jan 2021 18:36:03
User entered 'ARTHRALGIA IN MULTIPLE JOINTS' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:36:03
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of ARTHRALGIA. Please reconcile with the ConMed eCRF so there is an appropriate match.	(b) (4), (b) (6)	18 Jan 2021 02:24:01
' (Site from DM).		
User closed query 'Per DM CLR: Please note this AE overlaps with AE#1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.	(b) (4), (b) (6)	11 Dec 2020 11:02:42
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 23:52:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Dec 2020 23:52:50
Data point term sent to Coder	System	08 Dec 2020 23:52:22
Query 'Per DM CLR: Please note this AE overlaps with AE#1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.	Krishna Shah (b) (4)	08 Dec 2020 23:52:19
' answered with 'updated ' (Site from DM).	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Krishna Shah (b) (4)	08 Dec 2020 23:52:13
	(b) (4)	
User entered 'Arthralgia' reason for change: Data Entry Error	Krishna Shah (b) (4)	08 Dec 2020 23:52:13
	(b) (4)	
User opened query 'Per DM CLR: Please note this AE overlaps with AE#1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.	(b) (4), (b) (6)	06 Nov 2020 10:25:16
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 00:32:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 00:32:20
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 00:31:21
User entered 'Fatigue'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User closed query 'Per CDM: "To help clarify the clinical significance of the event (Administration site discomfort)and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling)." (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 16:56:35
Query 'Per CDM: "To help clarify the clinical significance of the event (Administration site discomfort)and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling)." answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:28:19
User opened query 'Per CDM: "To help clarify the clinical significance of the event (Administration site discomfort)and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling)." (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 21:52:17
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '00:00'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User entered '14 Sep 2020 00:00'	System	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)' reason for change: Data Entry Error	Krishna Shah (b) (4)	08 Dec 2020 23:52:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '22 Sep 2020' reason for change: Data Entry Error	Krishna Shah (b) (4)	08 Dec 2020 23:52:13
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 11:02:44
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:52:36
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 23:52:13
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User entered empty.	System	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'l'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:52:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User entered '0'	System	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22
User entered '0'	System	15 Oct 2020 00:30:32

US3822154

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:11
User entered	System	04 Jan 2021 16:18:02
'USA-US126-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	04 Jan 2021 16:18:02

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	31 Dec 2020 19:42:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Dec 2020 19:42:41
Data point term sent to Coder	System	31 Dec 2020 19:42:22
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	21 Jan 2021 16:13:03
User entered '28 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Dec 2020 19:42:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:42:08
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Dec 2020 19:41:32
User entered '16:45'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 19:42:08
User entered '28 Dec 2020 16:45'	System	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	19 Feb 2021 18:20:52
User closed query 'Per CRIO Source, SAE is ongoing. Please reconcile with EDC and update CRIO and/or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:20:49
Query 'Per CRIO Source, SAE is ongoing. Please reconcile with EDC and update CRIO and/or EDC as applicable.' answered with 'End date has been added to CRIO showing date of hospital discharge' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:24:29
User opened query 'Per CRIO Source, SAE is ongoing. Please reconcile with EDC and update CRIO and/or EDC as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:20:14
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 15:45:46
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	19 Feb 2021 18:20:47
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:46
User entered '09 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 15:45:46
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date updated' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:13:07
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 15:46:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:03:04
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject is still in the hospital therefore no date can be added at this time.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 21:01:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:27:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:50:06
	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
Query 'Per CDM: Re-query: Per site response " Subject is still inpatient". Hence please review and update the response 'Hospital Discharge Date' when available and route back DM review only after it was updated. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 22:41:33
User opened query 'Per CDM: Re-query: Per site response " Subject is still inpatient". Hence please review and update the response 'Hospital Discharge Date' when available and route back DM review only after it was updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 10:08:38
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Jan 2021 10:05:41
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still inpatient' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 19:42:35
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	31 Dec 2020 19:41:32
User entered 'I'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '28 Dec 2020'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:21:08
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:13:11
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 15:46:16
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:46
User entered '09 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 15:45:46
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:02:28
User closed query '(Pending MR) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 14:24:30
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 21:01:52
Query '(Pending MR) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Subject has not been discharged' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:27:38
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Subject has not been discharged' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:27:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query '(Pending MR) PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:49:32
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:49:15
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'No (N)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:21:24
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:13:30
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 15:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 15:45:46
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:02:07
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
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)	12 Jan 2021 21:02:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 21:02:01
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 21:01:57
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 'Subject is still in the hospital. This will be added once discharged.' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:32:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Subject is still in the hospital. This will be added once discharged.' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:32:01

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.'	Kelly Woodell (b) (4)	12 Jan 2021 14:31:39
answered with 'Updated' (Site from Safety).		
User entered 'Not Related (NOT RELATED)'	Kelly Woodell (b) (4)	12 Jan 2021 14:31:28
reason for change: Data Entry Error	(b) (4)	
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)	07 Jan 2021 15:50:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:50:14
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.'	(b) (4), (b) (6)	07 Jan 2021 15:49:07
(Site from Safety).		
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
DataPoint Verified.	System	27 Jan 2021 15:47:53
	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Dec 2020 19:41:32
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 15:24:12
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:47:53
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 15:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	19 Feb 2021 15:24:14
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:47:53
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 15:47:53
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered '0'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 15:24:42
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:13:34
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 15:48:11
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 15:45:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	27 Jan 2021 15:45:46
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:13:03
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:02:48
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 21:02:08
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject is still in the hospital. This will be added once discharged.' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:32:18
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:49:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 19:43:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Dec 2020 19:43:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 19:43:15
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 19:41:32
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:13:03
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
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) (4), (b) (6)	28 Jan 2021 14:13:44
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:13:40
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 14:13:36
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'This has been sent to safety on 27JAN2021' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 18:35:41
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 'Unable to find if COVID-19 testing was done in hospital.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 16:12:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Treatments have been added to conmeds and con procedures' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:10:06
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 Jan 2021 15:03:20
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:03:12
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 15:02:40
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 21:02:12

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject is still in the hospital. This will be added once discharged.' (Site from Safety).	Kelly Woodell (b) (4)	12 Jan 2021 14:33:07
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 15:49:40
User entered 'The subject presented to the emergency department on 28-DEC-2020 with chest tightness and was found to have had a recent heart attack. He was admitted and is still inpatient. SAE will be updated when records have been received.'	(b) (4), (b) (6)	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Dec 2020 19:41:32

US3822154

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Dec 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthmatic - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 18:09:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Mar 2021 18:09:48
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 15:28:56
User entered 'Asthmatic Symptoms'	(b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:54:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 15:27:58

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:20:16
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Yes. COVID negative' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 17:49:30
Query 'Per MM, please provide the end date.' canceled (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 14:04:05
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 04:58:55
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 04:58:44
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough increased - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 16:53:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 16:53:50
Data point term sent to Coder	System	02 Mar 2021 15:28:55
User entered 'More frequent coughing'	(b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:20:20
Query 'Per MM, please provide the end date.' answered with 'no end date yet' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 17:49:52
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 14:04:31
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 15:28:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 15:28:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 15:28:50
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 15:28:45
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:52:35
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:28:45

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 15:28:50

US3822154

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:54:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 15:28:45

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:54:53

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:53
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:03:29
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:26:16
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Query Resolved. Data was entered into medical history' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 17:14:08
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:23:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 00:01:59

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:03:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:03:17
Data point term sent to Coder	System	15 Oct 2020 00:02:56
User entered 'Wellbutrin'	(b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '150'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:02:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Dec 2020 02:11:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 02:11:45
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4)	08 Dec 2020 23:57:26 08 Dec 2020 23:56:41
User entered 'TESTOSTERONE CYPIONATE 200mg/ml oil' reason for change: Data Entry Error	Krishna Shah (b) (4)	08 Dec 2020 23:56:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:04:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:04:19
Data point term sent to Coder	System	15 Oct 2020 00:03:56
User entered 'Testosterone cypionate'	(b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Low Testosterone'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the expected dose/unit for this medication. Please update the dose ad unit as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 11:59:32
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the expected dose/unit for this medication. Please update the dose ad unit as appropriate, otherwise provide clarification. ' answered with 'update' (Site from DM).	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:56:52
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:56:41
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the expected dose/unit for this medication. Please update the dose ad unit as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 19:37:47
User entered '0.5'	(b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Krishna Shah (b) (4)	08 Dec 2020 23:56:41
Data Entry Error	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'application' reason for change: Data Entry Error	Krishna Shah (b) (4)	08 Dec 2020 23:56:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 1992'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	15 Oct 2020 00:03:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL, PRODUCTSYNONYM: CIALIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:04:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:04:19
Data point term sent to Coder	System	15 Oct 2020 00:03:57
User entered 'Cialis'	(b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'ED'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '10'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:03:38

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 05:34:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:34:22
Data point term sent to Coder	System	15 Oct 2020 00:04:58
User entered 'Ezopiclone'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Sleep apnea'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '3'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:04:01

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 13:49:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:49:31
Data point term sent to Coder	System	15 Oct 2020 00:04:58
User entered 'Alprozalam'	(b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Anxiety'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0.25'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:04:25

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 13:36:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:36:40
Data point term sent to Coder	System	15 Oct 2020 00:04:58
User entered 'Alfuzosin'	(b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:00:10
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:58:10
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 19:39:35
User entered 'Frequent urination'	(b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '5'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:04:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: NASACORT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Feb 2021 15:42:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 15:42:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOID, PRODUCT: BUDESONIDE, PRODUCTSYNONYM: NASOCORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 00:02:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 00:02:52
Data point term sent to Coder	System	09 Dec 2020 00:01:49
Data point term sent to Coder	System	09 Dec 2020 00:00:32
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:59:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOID, PRODUCT: BUDESONIDE, PRODUCTSYNONYM: NASOCORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:11:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:11:20
Data point term sent to Coder	System	15 Oct 2020 00:06:01
User entered 'Nasocort'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM). Query 'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:00:16
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:59:39
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:59:33
Query "'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.'	(b) (4), (b) (6)	27 Nov 2020 19:40:48
Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate.		27 Nov 2020 19:40:44
"		
' canceled (Site from DM).		
User opened query "'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.'	(b) (4), (b) (6)	27 Nov 2020 19:40:19
Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate.		
"		
' (Site from DM).		
User entered 'Allergies'	(b) (4), (b) (6)	15 Oct 2020 00:05:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '2'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. " ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:00:25
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. " ' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:01:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:01:00
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate. " ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 19:40:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:05:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Dec 2020 00:02:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 00:02:51
Data point term sent to Coder Coding entries removed.	System Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:00:32 08 Dec 2020 23:59:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:07:19
Data point term sent to Coder User entered 'Montelukast'	System (b) (4), (b) (6) (b) (4)	15 Oct 2020 00:06:00 15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

Indication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:00:36
"		
' (Site from DM).		
Query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:59:56
"		
' answered with 'updated ' (Site from DM).		
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:59:47
User opened query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	27 Nov 2020 19:41:46
"		
' (Site from DM).		
User entered 'Allergies'	(b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:05:42

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: VARIOUS, ATC: ALLERGENS, ATC: ALLERGENS, ATC: ALLERGEN EXTRACTS, PRODUCT: ALLERGENS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:08:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:08:20
Data point term sent to Coder	System	15 Oct 2020 00:07:02
User entered 'Allergy Injections'	(b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Allergies'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0.50'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'CC'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'every week (QS)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	15 Oct 2020 00:06:19

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:09:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:09:21
Data point term sent to Coder	System	15 Oct 2020 00:08:04
User entered 'Anastrozole'	(b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Low testosterone'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0.5'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '2x/week'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:07:11

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:31:44
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	12 Apr 2021 00:03:29
Data point term sent to Coder	System	09 Apr 2021 13:26:46
User closed query 'CDM-Coding: The trade name EXCEDRIN can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	System	09 Apr 2021 13:25:56
Query 'CDM-Coding: The trade name EXCEDRIN can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6) (b) (4)	09 Apr 2021 13:25:56
Data point term sent to Coder	System	09 Apr 2021 13:25:44
User entered 'EXCEDRIN - Acetaminophen, Aspirin, and Caffeine' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	09 Apr 2021 13:25:35
User opened query 'CDM-Coding: The trade name EXCEDRIN can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4) (b) (4)	09 Apr 2021 11:50:33
Data point term sent to Coder	System	05 Apr 2021 14:09:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
User closed query 'For coding purposes, term is not codable as entered. Please clarify the Con Med EXCERINE. If correct spelling, please provide the active ingredient, generic/trade name and update the eCRF . ' (Site from System).	System	05 Apr 2021 14:08:47
Query 'For coding purposes, term is not codable as entered. Please clarify the Con Med EXCERINE. If correct spelling, please provide the active ingredient, generic/trade name and update the eCRF . ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 14:08:47
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 14:08:30
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 14:08:30
User entered 'EXCEDRIN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:08:30
User opened query 'For coding purposes, term is not codable as entered. Please clarify the Con Med EXCERINE. If correct spelling, please provide the active ingredient, generic/trade name and update the eCRF . ' (Site from System).	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:14:29
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:37:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 22:37:35
Data point term sent to Coder	System	15 Oct 2020 00:08:03
User entered 'Excerine'	(b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Headaches'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:07:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 18:31:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:31:32
Data point term sent to Coder	System	09 Dec 2020 00:04:52
Data point term sent to Coder	System	09 Dec 2020 00:03:52
Data point term sent to Coder	System	09 Dec 2020 00:02:49
Coding entries removed.	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:02:43
User entered 'PREDNISONE 1%' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:02:43
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 04:49:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 04:49:20
Data point term sent to Coder	System	15 Oct 2020 00:10:04
User entered 'Prednisone'	(b) (4), (b) (6) (b) (4)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:00:50
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:04:29
User entered 'seasonal allergies' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:04:22
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 19:43:28
User entered 'Retina issues'	(b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Please note, 1 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of drops (e.g., Dose=1, If dose unit is Other, specify = drop) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:00:52
Query 'Per DM CLR: Please note, 1 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of drops (e.g., Dose=1, If dose unit is Other, specify = drop) would be more appropriate recording. If so, update eCRF as appropriate.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:03:29
User entered '1' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	09 Dec 2020 00:02:43
User opened query 'Per DM CLR: Please note, 1 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of drops (e.g., Dose=1, If dose unit is Other, specify = drop) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 19:43:59
User entered '1%'	(b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'application' reason for change: Data Entry Error	Krishna Shah (b) (4)	09 Dec 2020 00:02:43
	(b) (4)	
User entered '1%'	(b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Krishna Shah (b) (4)	09 Dec 2020 00:03:23
	(b) (4)	
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User entered 'ophthalmic' reason for change: Data Entry Error	Krishna Shah (b) (4)	09 Dec 2020 00:03:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:09:07

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:11:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:11:22
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	15 Oct 2020 00:10:05 15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement - heart health'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '175'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:09:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
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;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:12:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:12:22
Data point term sent to Coder	System	15 Oct 2020 00:11:06
User entered 'Glucosamine chondroitin'	(b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '1500-700'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:10:14

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:12:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:12:22
Data point term sent to Coder	System	15 Oct 2020 00:11:06
User entered 'Probiotic'	(b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:10:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:12:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:12:22
Data point term sent to Coder	System	15 Oct 2020 00:11:06
User entered 'Fiber'	(b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0.52'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:10:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DIGESTIVES, INCL. ENZYMES, ATC: DIGESTIVES, INCL. ENZYMES, ATC: ENZYME PREPARATIONS, PRODUCT: ALPHA-AMYLASE SWINE PANCREAS;CELLULASE;LIPASE;PROTEASE NOS, PRODUCTSYNONYM: DIGESTIVE ENZYME - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 05:30:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:30:24
Data point term sent to Coder	System	15 Oct 2020 00:12:06
User entered 'Digestive enzymes'	(b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '1'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:11:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: GINKGO BILOBA, PRODUCTSYNONYM: GINKO BILOBA [GINKGO BILOBA] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 05:36:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:36:22
Data point term sent to Coder	System	15 Oct 2020 00:12:06
User entered 'Ginko Bilboa'	(b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '24'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:11:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:14:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:14:23
Data point term sent to Coder	System	15 Oct 2020 00:13:07
User entered 'Vitamin C'	(b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '500'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:12:20

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 00:15:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 00:15:24
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 00:14:08
User entered 'Garlic'	(b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '4000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:13:15

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: KERATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 10:24:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 10:24:14
Data point term sent to Coder	System	15 Oct 2020 00:14:08
User entered 'Ceratine'	(b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '3'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:13:39

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:15:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:15:24
Data point term sent to Coder	System	15 Oct 2020 00:14:08
User entered 'Zinc'	(b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '50'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:14:03

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: VITAMIN K, PRODUCT: MENAQUINONE-7, PRODUCTSYNONYM: VITAMIN K2 MK7 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Oct 2020 03:46:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 03:46:29
Data point term sent to Coder	System	15 Oct 2020 00:15:09
User entered 'Vitamin K-2 MK7'	(b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '100'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:14:32

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D 3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:15:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:15:24
Data point term sent to Coder	System	15 Oct 2020 00:15:09
User entered 'Vitamin D-3'	(b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '2000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 00:14:53

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: EFINACONAZOLE, PRODUCTSYNONYM: JUBLIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 00:17:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:17:29
Data point term sent to Coder User entered 'Jublia'	System (b) (4), (b) (6)	15 Oct 2020 00:16:09 15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:15:34

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Oct 2020 00:17:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:17:29
Data point term sent to Coder	System	15 Oct 2020 00:16:09
User entered 'Valacyclovir'	(b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'HSV'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '500'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un UNK 1987'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 00:16:04

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	15 Oct 2020 00:18:15
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	15 Oct 2020 00:18:15
Data point term sent to Coders	System	15 Oct 2020 00:17:09
User entered 'Tdap'	(b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '01 May 2014'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '01 May 2014'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User entered empty.	System	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User entered empty.	System	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:31
User entered empty.	System	15 Oct 2020 00:16:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:03:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:03:20
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:23:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:23:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:19:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:19:16
Data point term sent to Coder	System	15 Oct 2020 00:18:10
User entered 'Influenza'	(b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '13 Feb 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '13 Feb 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User entered empty.	System	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User entered empty.	System	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:36
User entered empty.	System	15 Oct 2020 00:17:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:05:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 09:05:56
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTS YNOM: ZOSTER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:19:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 00:19:16
Data point term sent to Coder	System	15 Oct 2020 00:18:10
User entered 'Zoster'	(b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Vaccine'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'unk'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '01 Apr 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '01 Apr 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User entered empty.	System	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User entered empty.	System	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:40
User entered empty.	System	15 Oct 2020 00:17:46

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 13:49:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 13:49:30
Data point term sent to Coder	System	15 Oct 2020 00:23:15
User entered 'Aleve'	(b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES, 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 MUSCLE ACHES, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:01:09
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES, 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 MUSCLE ACHES, HEADACHE did not meet the AE reporting criteria. ' answered with 'med taken for solicited AEs that did not meet reporting criteria. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:54:55

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES, 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 MUSCLE ACHES, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 19:44:44
User entered 'Muscle aches, headache'	(b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '220'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 14:46:30
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User entered '1'	System	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User entered '1'	System	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:47:45
User entered '804 (804)'	System	15 Oct 2020 00:23:00

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 15:59:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 15:59:11
Data point term sent to Coder User entered 'Carvedilol'	System (b) (4), (b) (6)	27 Jan 2021 15:58:22 27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE of heart attack has already been added. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:29:29
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:52:36
User entered 'Heart Attack'	(b) (4), (b) (6)	23 Feb 2021 10:22:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '6.25'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:57:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Dec 2020 14:46:44

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Jan 2021 00:56:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 00:56:09
Data point term sent to Coder	System	27 Jan 2021 16:03:44
User entered 'Ellicus'	(b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Heart Attack'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '5'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 16:03:36

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Jan 2021 00:31:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 00:31:09
Data point term sent to Coder	System	27 Jan 2021 16:09:49
User entered 'Amiodarone'	(b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Heart Attack'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '200'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '2 tablets of 200mg oncw a day for 4 weeks'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 16:08:50

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 23:58:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 23:58:48
Data point term sent to Coder	System	02 Mar 2021 15:30:57
User entered 'Albuterol'	(b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'More frequent coughing and asthmatic symptoms'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '90'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'un Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 15:30:21

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 18:48:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:48:47
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	24 Mar 2021 18:47:18 24 Mar 2021 18:47:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 23:59:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 23:59:51
Data point term sent to Coder User entered 'Amlodipine'	System (b) (4), (b) (6)	02 Mar 2021 15:31:58 02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:47:01
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide comment for alternate/different use. Update eCRF as appropriate.	(b) (4), (b) (6)	19 Mar 2021 11:41:27
' (Site from DM).		
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide comment for alternate/different use. Update eCRF as appropriate.	(b) (4), (b) (6)	16 Mar 2021 13:12:56
' answered with 'this is correct per patient' (Site from DM).		
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide comment for alternate/different use. Update eCRF as appropriate.	(b) (4), (b) (6)	13 Mar 2021 13:21:40
' (Site from DM).		
User entered 'More frequent cough'	(b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:35:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:47:30
User entered '2.5' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 18:47:01
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 13:21:45
User entered '0.25'	(b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 17:47:36
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'prescribed for med hx of hypertension. Patients denies worsening of hypertension. MD preferred BP to be lower so Amlodipine was prescribed in addition to other cardiac medications previously prescribed.' (Site from DM).	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 18:58:59
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 13:21:53
User entered '23 Dec 2020'	(b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:54:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 15:31:33

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:54:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:53
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:41
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	08 Dec 2020 23:53:13

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:49:04

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Heart Cath'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:49:04

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:49:04

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:49:04

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:12
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:54:32

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:12
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Implantable Cardioverter Defibrillator'	(b) (4), (b) (6)	27 Jan 2021 15:54:32

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:12
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:54:32

US3822154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:23:12
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:51
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:54:32

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'USA-US126-2021-MRNA-1273-P301000001'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Christina'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Kennelly'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:04
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	05 Feb 2021 15:56:15
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:13:02
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:39:45
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:39:39
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:04:19

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:06
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:56:15
	(b) (4)	
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:07
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:09
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 21:02:29
User entered 'US'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Jan 2021 14:14:26
User entered '2'	System	12 Jan 2021 21:02:40
User entered '1'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'USA-US126-2021-MRNA-1273-P301000001'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Christina'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Kennelly'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:04
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:13:02
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:39:45
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:39:39
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:04:19

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:06
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:56:15
	(b) (4)	
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:07
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:09
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 21:02:29
User entered 'US'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Jan 2021 14:14:26
User entered '2'	System	12 Jan 2021 21:02:40
User entered '1'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:54:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
User entered '04/Jan/2021 16:18'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:54:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 21:02:29
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'USA-US126-2021-MRNA-1273-P301000001'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Christina'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Kennelly'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:04
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:13:02
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:39:45
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:39:39
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:04:19

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:06
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:56:15
	(b) (4)	
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:07
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:09
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 21:02:29
User entered 'US'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Jan 2021 14:14:26
User entered '2'	System	12 Jan 2021 21:02:40
User entered '1'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:54:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
User entered '12/Jan/2021 21:02'	System	12 Jan 2021 21:02:40

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:54:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 16:03:45
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 21:02:40

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'USA-US126-2021-MRNA-1273-P301000001'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Yes (Y)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'No (N)'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Christina'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 16:18:22
User entered 'Kennelly'	System	04 Jan 2021 16:18:02

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:04
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4)	05 Feb 2021 15:56:15
reason for change: Data Entry Error	(b) (4)	
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User closed query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:13:02
Query 'Please complete each individual field for address.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:39:45
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:39:39
User opened query 'Please complete each individual field for address.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:04:19

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:06
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	05 Feb 2021 15:56:15
	(b) (4)	
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:07
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:09
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	05 Feb 2021 15:56:15
Un-reviewed for Safety.	System	28 Jan 2021 14:14:26
User entered empty.	System	28 Jan 2021 14:14:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 14:13:57
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:39:39

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:03:45
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 21:02:29
User entered 'US'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Jan 2021 14:14:26
User entered '2'	System	12 Jan 2021 21:02:40
User entered '1'	System	04 Jan 2021 16:18:27

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:54:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:15
User entered '28/Jan/2021 14:14'	System	28 Jan 2021 14:14:26

US3822154

Folder: SAE USA-US126-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:54:53

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:06:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:43:15
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 14:14:26